

<b>SOLICITATION, OFFER AND AWARD</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)		RATING		PAGE OF 1   29 PAGES			
2. CONTRACT NO.		3. SOLICITATION NO. 2000-N-00073		4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input checked="" type="checkbox"/> NEGOTIATED (RFP)		5. DATE ISSUED 30 May 00		6. REQUISITION/PURCHASE NO.	
7. ISSUED BY Centers for Disease Control and Prevention (PGO)1Contracts Management Branch12920 Brandywine Rd, Rm 30001Atlanta, GA 30341-55391				8. ADDRESS OFFER TO (If other than Item 7)					

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder."

### SOLICITATION

9. Sealed offers in original and 8 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if hand carried, in the depository located in Colgate Bldg, 2920 Brandywine Rd, Rm 3000, Atlanta GA 30341 until 2:00p local time Jun 29, 2000  
(Hour) (Date)

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-10. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME Kem Williams	B. TELEPHONE NO. (Include area code) (NO COLLECT CALLS) (770) 488-2776
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### OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 120 calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52-232-8)		10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS %
14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):		AMENDMENT NO.	DATE	AMENDMENT NO.	DATE
15A. NAME AND ADDRESS OF OFFEROR		CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER (Type or Print)	
15B. TELEPHONE NO. (Include area code)		<input type="checkbox"/> 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.		17. SIGNATURE	
				18. OFFER DATE	

### AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED		20. AMOUNT		21. ACCOUNTING AND APPROPRIATION	
22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c)( ) <input type="checkbox"/> 41 U.S.C. 253(c)( )				23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified)	
24. ADMINISTERED BY (If other than Item 7)		CODE 7523		25. PAYMENT WILL BE MADE BY CODE 4342	
Centers for Disease Control and Prevention (CMB)12920 Brandywine Rd, Rm 30001Atlanta, GA 30341-55391				Centers for Disease Control and Prevention (FMO)1PO Box 155801Atlanta, GA 30333-1	
26. NAME OF CONTRACTING OFFICER (Type or print)				27. UNITED STATES OF AMERICA (Signature of Contracting Officer)	
				28. AWARD DATE	

IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.

## Section B - Supplies Or Services And Prices/Costs

ITEM	SUPPLIES / SERVICES	QUANTITY / UNIT	UNIT PRICE	EXTENDED PRICE NOT TO EXCEED:
0001	High-Speed Needle-Free Device for Measles Vaccination	1 Job		

Cost Plus Fixed Fee Line Items. Base Contract.

CLIN/SLIN	ESTIMATED COST	FIXED FEE	TOTAL EST. CPFF
0001			
Total			\$

### B.1 HHSAR 352.232-74 Consideration -- Estimated Cost and Fixed Fee (Apr 1984)

(a) It is estimated that the total cost to the Government for full performance of this contract will be \$ , of which the sum of \$ represents the estimated reimbursable costs and \$ represents the fixed-fee.

(b) Total funds currently available for payment and allotted to this contract are \$ , of which \$ represents the estimated reimbursement costs and \$ represents the fixed-fee. For further provisions on funding, see the Limitations of Funds clause.

(c) It is estimated that the amount currently allotted will cover performance of Phases , which is/are scheduled to be completed by .

(d) The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

(End of Clause)

## Section C - Description/Specification/Work Statement

### C.1 Statement of Work (Jul 1999)

#### I. Project Identification: High-Speed Needle-Free Device for Measles Vaccination

The project is to support the research and development (R&D) of a safe needle-free jet injector device capable of vaccinating large numbers of persons by limited manpower in short periods of time for use in epidemic control and eradication campaigns.

#### II. Background:

Worldwide accelerated measles control and potential eradication face obstacles related to safety and logistical difficulties in using needles and syringes for vaccination. Current vaccination for measles differs greatly from that used for polio and smallpox eradication. Oral polio vaccine is administered quickly and easily by lay individuals, and there is no danger of needle stick injury or un-sterile reuse of syringes and needles.

The expertise needed to load conventional syringes and inject measles vaccine with needles requires trained health personnel and raises a barrier to conducting nationwide mass vaccination activities for measles control or elimination. Ever since a 1985-86 hepatitis B outbreak in California, which was caused by a cross-contaminating jet injector and because of disconcerting results from recent animal model studies, the safety of previous generations of high-speed jet injector “guns” used for mass vaccination campaigns (e.g., previous Med-E-Jet®, Ped-O-Jet®, or Dermo-Jet™ models) has been questioned due to the potential transfer of infectious blood borne pathogens between consecutive vaccinees. (For references, see: <http://www.cdc.gov/nip/dev/jetinject.htm#bibliography>)

#### III. Project Goals and Objectives

The overall goals of this initiative are to facilitate the availability for purchase on the commercial market in both the U.S. and developing countries of one or more safe, high-speed vaccination devices which are suitable for measles control and eradication campaigns. Specific objectives of this contract are to design, build, test at the bench and in animals and humans, and prepare for mass production and regulatory approval of a high-speed, needle-free injector device (and associated peripheral accessories and devices) for mass immunization campaigns which could use conventional, off-the-shelf lyophilized formulations of measles (MEA) or MMR (measles-mumps-rubella combination) vaccine, according to detailed performance specifications to be cited elsewhere in the contract solicitation. Specific product deliverables will be required for each phase of the contract duration.

##### A) Performance Specifications:

- 1) permits a single vaccinator to vaccinate parenterally up to 600 patients per hour with liquid measles or similar conventional vaccine (every-6-second cycling time), not counting staff and time needed for applying pressure bandages on injection site, or handling patient flow, paperwork, separately pre-filling injector cartridges with vaccine, etc;
- 2) be portable and not cause excessive user fatigue for up to one hour of continuous use by the worker;
- 3) be of inherently safe design (e.g., such as by using disposable, one-use-only nozzles, cartridges, or fluid pathways), specifically avoiding reusable nozzles and reusable fluid pathways and other designs with the potential for transfer of infectious blood or tissue fluid between consecutive vaccinees.

- 4) be appropriate for use in children of the target age for measles and rubella immunization (9 months through 15 years of age);
- 5) be usable by staff with less than medical or nursing training, after suitable training with device;
- 6) avoid any “sharps” hazards for needle stick in the disposal of non-reusable components; and thus require no specialized incineration or similar special disposal methods for the same
- 7) demonstrate a tolerable safety profile in terms of pain, tissue reactions, and other adverse effects;
- 8) demonstrate a satisfactory immune response in children 9 to 15 months of age to measles (MEA), or measles, mumps, rubella (MMR) vaccines.
- 9) be adaptable with some models for manual or pedal operation for use in developing countries where mains (wall) electric current and/or replacement batteries may not be reliable or available;
- 10) be designed and developed through the scope-of-work phases (see below) in accordance with proper management practices, quality controls, and validated methods which are in conformance with international and national standards for same (i.e., ISO 9001), in order to facilitate and permit registration and approval of the manufacture, marketing and sale of the device by the U.S. FDA or equivalent governmental authorities in other countries or regions.

#### **IV. Scope of Work Phases**

##### **Phase A. Initial Design:**

The contractor shall design detailed computer assisted drawings (CAD) after acquiring the following background information: study of existing device technology, immunization program requirements, clinical vaccinator (nurse) input, patent searches and resulting intellectual property licensing. This can include the building and testing of separate components for individual functionality.

##### **Phase B. Initial Prototype:**

The contractor shall manufacture and assemble the components and build a functional device, and perform or sub-contract for standardized bench testing of same for various physical parameters of its performance profile.

##### **Phase C. Working Prototype(s):**

The contractor shall build four or more devices suitable for actual animal and human studies by in-house staff or external subcontractors to assess and report its performance in such studies.

##### **Phase D. Animal and Cadaver Studies:**

The contractor shall conduct or subcontract for studies using suitable experimental animals (e.g., piglets <=10kg in weight) and human cadavers to assess dose penetration and dispersion, or provide existing data for same.

##### **Phase E. Develop data from human testing in adults:**

The contractor shall conduct (or subcontract for) tests of the device in adults for safety, depth and dispersion of injectate, and user ergonomics under investigational device exemption (IDE) authorization

from the U.S. FDA, and with prior approvals of institutional review boards for human subjects research at CDC and at the institution(s) where the clinical research is to be conducted.

**Phase F. Develop data from human testing in children:**

The contractor shall conduct (or subcontract for) tests of the device in children from 9 to 15 months of age under U.S. FDA investigational new drug (IND) authorization for safety, reactogenicity, and immunogenicity to MEA, MUM, and RUB antigens, patient visual and aesthetic acceptance, tolerability, and user ergonomics.

**Phase G. Field Testing:**

The contractor shall undertake (or subcontract for), in consultation with CDC, field testing of the devices on human subjects in a suitable measles-endemic country for use in measles mass-campaign “national immunization days” in which thousands of patients each day must be vaccinated against measles at vaccination sites. Such field testing shall include assessing the ease of use and practicality of the device, its commercial feasibility, and -- on a smaller subset of patients -- its immunogenicity for measles and safety for immediate and delayed localized reactions. Such field trials shall be conducted under the authority and approval of both local and CDC-based IRBs, and shall also meet NIH Office of Protection from Research Risks (OPRR) standards for ethical human testing.

**Phase H. Final design and regulatory documentation:**

The contractor shall prepare detailed drawings and manufacturing specifications of the final design selected for mass production and commercial sale, and shall prepare documentation for submission to regulatory authorities for approval of marketing and sales, or shall specify plans for further studies and research it deems necessary for development and commercialization to proceed.

V. **Reporting and Deliverables Requirements:**

A. **Quarterly Progress Reports**

The Contractor shall provide quarterly written progress reports to the Government by the 15<sup>th</sup> day after each calendar quarter ends. The reports will describe and include:

- (1) Work accomplished in the quarterly period covered.
- (2) Deliverables falling due within the period covered by the quarterly report.
- (3) Details and arrangements for work planned or scheduled on tasks anticipated by the Statement of Work for the succeeding quarter.
- (4) Current and anticipated problems and obstacles that will impact Contractor’s performance.
- (5) Proposed solutions in response to current and anticipated problems.

The Contractor shall provide two (2) copies of each quarterly report; one report each will be sent to the Project Officer and to the Contracting Officer.

**B. Deliverables**

The additional deliverables specified for each phase in section IV shall be submitted in advance or simultaneously with the quarterly report for the corresponding period during which the deliverable falls due. Document deliverables should include a summary, data synopsis, and all other relevant information about the work performed in that phase, and shall provide projections of the time frame for remaining phases. Device deliverables should be accompanied by instructions for use, and shall be returned upon request to the contractor.

**C. Draft Final Report**

The Contractor shall provide a draft final report no later than forty-five days prior to the expiration date of this contract for review by the Government. The draft report shall provide a written summary highlighting major accomplishments under the contract. The report should include a detailed compilation of the main data, observations, findings, and other relevant information about the device and testing performed. It shall also include a listing of patents applied for or awarded as result of work performed under the contract. It shall also provide projections of the time frame for future steps and commercial marketing and distribution, and further innovation. The report should be written in such a way as to provide an objective review of contract activities. The Contractor shall provide two (2) copies of the draft final report; one copy each will be sent to the Project Officer and the Contracting Officer.

**D. Final Report**

Following review of the draft final report by the Government, and receipt by the Contractor of the Government's written comments, the contractor shall provide a final report on or before the expiration date of the contract. The Contractor shall provide two (2) copies of the report; one report each will be sent to the Project Officer and to the Contracting Officer.

**E. Reference Materials**

1. Centers for Disease Control and Prevention, National Immunization Program website on needle-free injection: [www.cdc.gov/nip/dev/jetinject.htm](http://www.cdc.gov/nip/dev/jetinject.htm)
2. Privacy Act, Federal Register System Notification Number 09-200136/Vol. 57. No. 252/Thursday, December 31, 1992/Notices

## **Section D - Packaging And Marking**

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## **Section E - Inspection And Acceptance**

**FAR SOURCE**  
52.246-9

**TITLE AND DATE**  
Inspection of Research and Development (Short Form) (Apr 1984)

### **E.1 Inspection and Acceptance (Jul 1999)**

Inspection and acceptance of the articles, services, and documentation called for herein shall be accomplished by the Contracting Officer, or his duly authorized representative (who for the purposes of this contract shall be the Project Officer) at the destination of the articles, services or documentation.

(End of Clause)



## Section F - Deliveries Or Performance

<b>FAR SOURCE</b>	<b>TITLE AND DATE</b>
52.242-15	Stop-Work Order (Aug 1989)
52.242-15 Alternate I	(Apr 1984)

### F.1 Deliverable(s) Schedule (Jul 1999)

The Contractor shall deliver, within the time frames specified, Item(s) No. 1-13 to the Project Officer at the address shown in Section G, and Item(s) No. 1 to the Contracting Officer at the address shown on the face page of the contract. All quarterly reports and accompanying deliverables shall be provided no later than 15 calendar days after the end of the calendar year quarter. DELIVERABLES OTHER THAN QUARTERLY REPORTS SHALL BE DUE AT THE SAME TIME AS THE QUARTERLY REPORT COVERING THE PERIOD FOR WHICH THE DELIVERABLE DEADLINE IS STATED. However, deliverables which are completed prior to the deadlines below may be submitted at any earlier time, or may accompany an earlier quarterly report, at the contractor's discretion.

ITEM	DELIVERABLE	QUANTITY	TIME
1	Quarterly progress reports as specified in Scope of Work item no. V-A.	2 copies to Project Officer, 1 to Contracting Officer	Reports due upon the end of each calendar quarter occurring more than 45 days after contract award date
<b>Phase A: Initial Design</b>			
2	Report of information on existing device technology, immunization program requirements, clinical vaccinator (nurse) input, patent searches and resulting intellectual property licensing requirements, if any.	2 copies to Project Officer	3 months after contract award date (submitted with corresponding quarterly report)
<b>Phase B: Initial Prototype</b>			
3	Design of detailed computer assisted drawings of an initial prototype device, including cartridges and filling devices, if required.	2 copies to Project Officer	6 months after contract award date (submitted with corresponding quarterly report)
4	A functional initial prototype device, prototype accessories (e.g., cartridges), and filling devices, if required.	1 device to Project Officer (to be returned)	9 months after contract award date (submitted with corresponding quarterly report)
5	Report of standardized bench testing of initial or modified prototype device for various physical parameters and in vitro performance.	2 copies to Project Officer	10 months after contract award date (submitted with corresponding quarterly report)
<b>Phase C: Working Prototypes</b>			
6	Four or more working devices and a supply of sterilizable cartridges and required filling devices suitable for actual animal and human studies.	2 devices to Project Officer (to be returned)	12 months after contract award date (submitted with corresponding quarterly report)

<b>Phase D: Animal and Cadaver Studies</b>			
7	Report of studies using suitable experimental animals (e.g., piglets <=10kg in weight) and human cadavers to assess dose penetration and dispersion.	2 copies to Project Officer	15 months after contract award date (submitted with corresponding quarterly report)
<b>Phase E: Develop Data from Human Testing in Adults</b>			
8	Report on completed tests of the device in adults.	2 copies to Project Officer	20 months after contract award date (submitted with corresponding quarterly report)
<b>Phase F: Develop Data from Human Testing in Children</b>			
9	Report on completed tests of the device in children	2 copies to Project Officer	26 months after contract award date (submitted with corresponding quarterly report)
<b>Phase G: Field Testing</b>			
10	Report on field testing of the devices in human subjects in mass vaccination campaign in a developing country.	2 copies to Project Officer	32 months after contract award date (submitted with corresponding quarterly report)
<b>Phase H: Final design and documentation for regulatory device approval</b>			
11	Summary of drawings and manufacture specifications for mass production of devices for commercial sale, and summary of documents prepared for submission to regulatory authorities for approval of marketing and sales.	2 copies to Project Officer	36 months after contract award. date (submitted with corresponding quarterly or final report)
12	Draft Final Report as specified in Scope of Work item no. V-C	3 copies to Project Officer	45 days before the contract completion date
13	Final Report as specified in Scope of Work item no. V-D.	4 copies to Project Officer and 1 copy to Contracting Officer	No later than the contract completion date

(End of Clause)

## **F.2 Period of Performance (Jul 1999)**

The period of performance shall be a period of 36 months.

(End of Clause)

## **Section G - Contract Administration Data**

### **G.1 Payments by Electronic Funds Transfer (Jan 2000)**

(a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration, incorporated by reference in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

(b) The contractor shall make the designation by submitting the form titled “ACH Vendor/Miscellaneous Payment Enrollment Form” to the address indicated below. Note: The form is either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer or the CDC Financial Management Office at (404) 687-6666.

(c) In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required.

(d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

Centers for Disease Control and Prevention  
Financial Management Office  
P.O. Box 15580 MS: D06  
Atlanta, GA 30333

(End of Clause)

### **G.2 Voucher Submission (Cost Reimbursement) (Apr 2000)**

(a) Contractor voucher requests for reimbursement shall conform to the form, format, and content requirements of the Billing Instructions for Negotiated Cost Type Contracts, made a part of the contract in Section J, as may be supplemented by specific instructions of the Contracting Officer.

(b) The Contractor shall submit an original and 4 copies of contract invoices/vouchers to the address shown below:

Centers for Disease Control and Prevention  
Procurement and Grants Office  
Contracts Management Branch  
2920 Brandywine Road, Room 3000  
Atlanta, GA 30341

(c) The contractor ☒ is, ☐ is not, required to provide a copy of each of its voucher requests for reimbursement to the Project Officer ( or to the Task Order Project Officer or Technical Monitor if this is a task order contract) concurrently with submission to the Contracting Officer.

(d) The Contractor shall, in addition to the above requirements, submit a detailed breakout of costs as supporting backup and shall place the following signed Contractor Certification on each invoice/voucher submitted under this contract:

I certify that this voucher reflects                      request for reimbursement of allowable and allocable costs incurred in specific performance of work authorized under Contract                      /Task                      , and that these costs are true and accurate to the best of my knowledge and belief.

\_\_\_\_\_  
(Original Signature of Authorized Official)  
Typed Name and Title of Signatory

(e) The date of receipt of a proper invoice/voucher by the Contracting Officer shall be used for the purpose of Prompt Payment Act time computations.

(End of Clause)

### **G.3 Reimbursement of Cost (Jul 1999)**

(a) For the performance of this contract, the Government shall reimburse the Contractor the cost (hereinafter referred to as allowable cost) determined by the Contracting Officer to be allowable in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses. Examples of allowable costs include, but are not limited to, the following:

(1) All direct materials and supplies which are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

(2) All direct labor, including supervisory , that is properly chargeable directly to the contract, plus fringe benefits.

(3) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

(4) Special expenditures which, upon request from the Contractor, the Contracting Officer approves as being an allowable cost under this contract.

(5) All travel costs plus per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract. These costs will be in accordance with the Contractor's policy and subject to the following:

(i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

(ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

(iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Joint Travel Regulation (JTR).

(iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) JTR established mileage rate.

(v) Consultant services in an amount not to exceed \$TBD.

(b) Except as stated herein, the Contractor shall not incur costs unless the prior written authorization of the Contracting Officer has been obtained. When costs are incurred without such prior authorization, with the intent of claiming reimbursement as direct costs, it shall be at the contractor's risk.

(End of Clause)

#### **G.4 Payments (Jul 1999)**

The cost of the work to be performed by the Contractor under this contract (exclusive of the fixed-fee) is estimated at \$ . The Contractor shall receive a fixed-fee of \$ for a total estimated cost-plus-fixed-fee of \$ . The Contractor shall invoice for his fixed-fee in accordance with the clause of Section I entitled "Fixed-Fee" - FAR 52.216-08. Subject to the provisions of the clause entitled "Allowable Cost and Payment" of Section I, payments shall be made on a monthly basis as work progresses. After payment of 85% of the fixed-fee, as provided for in the clause entitled "Fixed-Fee" - FAR 52.216-08 of Section I, further payment on account of the fixed-fee shall be withheld until final payment.

(End of Clause)

#### **G.5 Contracting Officer (Jul 1999)**

(a) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

(b) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

(End of Clause)

#### **G.6 Contract Communications/Correspondence (Jul 1999)**

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

(End of Clause)

#### **G.7 Technical Monitoring (July 1999)**

(a) Performance of the work under this contract shall be subject to the technical monitoring of the Project Officer. The term "Technical Monitoring" is defined to include, without limitation, the following:

(1) Technical directions to the Contractor which redirect the contract effort, shift work emphasis between work areas or tasks, require pursuit of certain lines of inquiry, fill in details or otherwise serve to accomplish contractual scope of work.

(2) Providing information to the Contractor for assistance in the interpretation of drawings, specifications or technical portions of the work description.

(3) Review and, where required by the contract, approve of technical reports, drawings, specifications and technical information to be delivered by the Contractor to the Government under the contract.

(b) Technical direction must be within the general scope of work stated in the contract. The Project Officer does not have the authority to and may not issue any technical direction which (i) constitutes an assignment of additional work outside the general scope of the contract; (ii) constitutes a change as defined in the contract

clause entitled "Changes"; (iii) in any manner causes an increase or decrease in the total contract cost, the fixed fee or the time required for contract performance; or (iv) changes any of the express terms, conditions, or specifications of the contract.

(c) All technical directions shall be issued in writing by the Project Officer or shall be confirmed by him/her in writing within five (5) working days after issuance.

(d) The Contractor shall proceed promptly with the performance of technical directions duly issued by the Project Officer in the manner prescribed by this article and within his/her authority under the provisions of this clause.

(e) If, in the opinion of the Contractor, any instruction or direction issued by the Project Officer is within one of the categories as defined in (b)(3)(i) through (iv) above, the Contractor shall not proceed but shall notify the Contracting Officer in writing within five (5) working days after the receipt of any such instruction or direction and shall request the Contracting Officer to modify the contract accordingly. Upon receiving such notification from the Contractor, the Contracting Officer shall issue an appropriate contract modification or advise the Contractor in writing that, in his/her opinion, the technical direction is within the scope of this clause and does not constitute a change under the Changes clause of the contract. The Contractor shall thereupon proceed immediately with the direction given. A failure of the parties to agree upon the nature of the instructions or direction or upon the contract action to be taken with respect thereto shall be subject to the provisions of the contract clause entitled "Disputes".

## **G.8 Project Officer (July 1999)**

- (a) Performance of the work hereunder shall be subject to the technical directions of the designated Project Officer for this contract.
- (b) As used herein, technical directions are directions to the Contractor which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor feels that full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer in a letter separate of any required report(s) within two (2) weeks of the date of receipt of the technical direction and no action shall be taken pursuant to the direction. If the Contractor fails to provide the required notification within the said two (2) week period that any technical direction exceeds the scope of the contract, then it shall be deemed for purposes of this contract that the technical direction was within the scope. No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.
- (c) The Government Project Officer is not authorized to change any of the terms and conditions of this contract. Changes shall be made only by the Contracting Officer by properly written modification(s) to the contract.
- (d) The Government will provide the Contractor with a copy of the delegation memorandum for the Project Officer. Any changes in Project Officer delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

## **G.9 Subcontracting Program Reports (May 1998)**

(a) The Contractor shall submit the reports listed below in accordance with the instructions and within the time periods specified on the report forms:

(1) Standard Form 294, Subcontracting Report for Individual Contracts.

(2) Standard Form 295, Summary Subcontract Report.

(b) In addition to the reporting information specified on the report forms, the Contractor shall provide, in the "Remarks" block on each Standard Form 294 submitted, a narrative of the progress made in fulfilling the small business and small disadvantaged business subcontracting goals contained in its approved plan.

(c) The Contractor shall report to the Contracting Officer any difficulties encountered in achieving the goals and shall describe the action being taken to overcome the difficulties.

(End of Clause)

## **G.10 Project Director**

Work and services will be conducted under the direction of \_\_\_\_\_. The Government reserves the right to approve any necessary successor to the Project Director.

(End of Clause)

## **G.11 Project Officer**

\_\_\_\_\_ is hereby designated as the Project Officer for this contract. The Project Officer is responsible for guiding the technical aspects of the project. The Project Officer shall not make any commitments or authorized any changes that affect the contract price, terms, or conditions; any such changes shall be referred to the Contracting Officer for action.

## **Section H - Special Contract Requirements**

### **H.1 HHSAR 352.270-5 Key Personnel (Apr 1984)**

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.

(End of Clause)

### **H.2 Prohibition on the Use of Appropriated Funds for Lobbying Activities (Jul 1999)**

The contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

(End of Clause)

### **H.3 Representations, Certifications and Other Statements of Offerors (Jul 1999)**

The Representations, Certifications and Other Statements of Offerors submitted by \_\_\_\_\_ dated \_\_\_\_\_ are hereby incorporated by reference, with the same force and effect as if they were given in full text.

(End of Clause)



#### **H.4 Office Equipment (May 1998)**

Notwithstanding any other provision of this contract, the Contractor shall not purchase or lease under this contract any items of office equipment, including office furniture or machines. Recovery of the cost of such items shall be allowable only to the extent that it is properly allocable in the indirect cost charged to this contract.

(End of Clause)

#### **H.5 Year 2000 Compliance (Jul 1999)**

Unless elsewhere exempted, information technology (if any) to be acquired under this contract/purchase order, which will be required to perform date/time processing involving dates subsequent to December 31, 1999, shall be Year 2000 compliant as defined in Federal Acquisition Regulation Part 39.002.

(End of Clause)

#### **H.6 Dissemination of Information (May 1998)**

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Project Officer.

(End of Clause)

#### **H.7 Identification of Data (May 1998)**

The Contractor shall identify the technical data delivered to the Government as required by this contract with the number of the contract and the name and address of the Contractor or subcontractor that generated the data.

(End of Clause)

#### **H.8 Identification and Disposition of Prototype and Reports**

All prototype samples and reports expected to be generated through the work described in the Contract shall be delivered to the Government at specified times during the contract period (see Delivery Schedule). The contractor will own the prototype device(s) submitted as deliverables, and the Center for Disease Control and Prevention will return it (them) to the contractor, upon its request, within 60 days after the due date for its delivery, or the actual date of delivery, whichever occurs later.

(End of Clause)

#### **H.9 Review and Comment (May 1998)**

All materials developed or information of whatever nature resulting from work performed under this contract shall be submitted to the Project Officer for review and comment prior to publication or dissemination.

(End of Clause)

## **H.10 Subcontracting Plan (July 1999)**

The Contractor's subcontracting plan, as negotiated, submitted in response to Solicitation 2000-N-00073, is hereby incorporated into this contract by reference.

(End of Clause)

## **H.11 Incorporation of Technical Proposal (May 1998)**

The Contractor's technical proposal, including all revisions thereto, submitted in response to RFP 2000-N-00073 is hereby incorporated into the contract by reference. The Contractor shall perform the work substantially as set forth in the technical proposal. Any revisions to the technical proposal that would significantly alter the technical approach must be approved in writing by the Contracting Officer. In the event of a conflict between Section C, Statement of Work, and the Contractor's technical proposal, Section C will take precedence.

(End of Clause)

## **H.12 Notice of Restricted Award – Live Vertebrates (April 2000)**

Under governing regulations, federal funds which are administered by the Centers for Disease Control and Prevention (CDC) shall not be expended by the contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of issuance of this award and is approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 and receive OPRR approval before expenditure of funds or involvement of live vertebrate animals. The present award is being made without OPRR-approved assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the contractor or individual performance sites pending OPRR approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28.

(End of Clause)

## **H.13 Privacy Act Applicability**

(a) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations is attached at Section J.

(b) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

(c) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act system notice provided in Section J, List of Attachments.

(End of Clause)

#### **H.14 HHSAR 352.270-8B Protection of Human Subjects (Jan 1999)**

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), Public Health Service. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgement or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting officer determines, in consultation with the OPRR, NIH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Health and Human Services Human Subject Assurances.

(End of Clause)

#### **H.15 HHSAR 352.270-9B Care of Live Vertebrate Animals (Jan 1999)**

(a) Before undertaking performance of any contract involving animal related activities, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH,

terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved PHS Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

## Section I - Contract Clauses

### Section I-1 - Clauses Incorporated By Reference

#### I.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://www.arnet.gov/far/>  
<http://farsite.hill.af.mil/vffar/htm>

(End of Clause)

<b>FAR SOURCE</b>	<b>TITLE AND DATE</b>
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Jan 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Jun 1997)
52.203-3	Gratuities (Apr 1984)
52.203-5	Covenant Against Contingent Fees (Apr 1984)
52.203-7	Anti-Kickback Procedures (Jul 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Jan 1997)
52.204-4	Printing/Copying Double-Sided on Recycled Paper (Jun 1996)
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jul 1995)
52.215-10	Price Reduction for Defective Cost or Pricing Data (Oct 1997)
52.215-11	Price Reduction for Defective Cost or Pricing Data -- Modifications (Oct 1997)
52.215-12	Subcontractor Cost or Pricing Data (Oct 1997)
52.215-13	Subcontractor Cost or Pricing Data -- Modifications (Oct 1997)
52.215-17	Waiver of Facilities Capital Cost of Money (Oct 1997)
52.215-2	Country Audit and Records -- Negotiation (Jun 1999)
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data -- Modifications (Oct 1997)
52.215-21 Alternate I	(Oct 1997)
52.215-8	Order of Precedence -- Uniform Contract Format (Oct 1997)
52.216-7	Allowable Cost and Payment (Mar 2000)
52.216-8	Fixed Fee (Mar 1997)
52.219-23	Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (Oct 1999)
52.219-25	Small Disadvantaged Business Participation Program -- Disadvantaged Status and Reporting (Oct 1999)
52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Jan 1999)
52.219-8	Utilization of Small Business Concerns (Oct 1999)
52.222-1	Notice to the Government of Labor Disputes (Feb 1997)
52.222-2	Payment for Overtime Premiums (Jul 1990)
52.222-26	Equal Opportunity (Feb 1999)
52.222-3	Convict Labor (Aug 1996)
52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (Apr 1998)
52.222-36	Affirmative Action for Workers with Disabilities (Jun 1998)
52.222-37	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era (Jan 1999)

52.223-6	Drug-Free Workplace (Jan 1997)
52.224-1	Privacy Act Notification (Apr 1984)
52.224-2	Privacy Act (Apr 1984)
52.225-13	Restrictions on Certain Foreign Purchases (Feb 2000)
52.227-1	Authorization and Consent (Jul 1995)
52.227-1 Alternate I	(Apr 1984)
52.227-14	Rights in Data -- General (Jun 1987)
52.227-14 Alternate I	(Jun 1987)
52.227-16	Additional Data Requirements (Jun 1987)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Aug 1996)
52.227-23	Rights to Proposal Data (Technical) (Jun 1987)
52.227-3	Patent Indemnity (Apr 1984)
52.230-2	Cost Accounting Standards (Apr 1998)
52.230-3	Disclosure and Consistency of Cost Accounting Practices (Apr 1998)
52.230-6	Administration of Cost Accounting Standards (Nov 1999)
52.232-17	Interest (Jun 1996)
52.232-22	Limitation of Funds (Apr 1984)
52.232-23	Assignment of Claims (Jan 1986)
52.232-25	Prompt Payment (Jun 1997)
52.232-34	Payment by Electronic Funds Transfer -- Other Than Central Contractor Registration (May 1999)
52.233-1	Disputes (Dec 1998)
52.233-3	Protest After Award (Aug 1996)
52.233-3 Alternate I	(Jun 1985)
52.242-1	Notice of Intent to Disallow Costs (Apr 1984)
52.242-13	Bankruptcy (Jul 1995)
52.242-3	Penalties for Unallowable Costs (Oct 1995)
52.242-4	Certification of Final Indirect Costs (Jan 1997)
52.243-2 Alternate V	(Apr 1984)
52.243-6	Change Order Accounting (Apr 1984)
52.244-5	Competition in Subcontracting (Dec 1996)
52.245-5	Government Property (Cost-Reimbursement, Time-and-Material, or Labor-Hour Contracts) (Jan 1986)
52.246-23	Limitation of Liability (Feb 1997)
52.249-14	Excusable Delays (Apr 1984)
52.249-6	Termination (Cost-Reimbursement) (Sep 1996)
52.253-1	Computer Generated Forms (Jan 1991)
<b>HHSAR SOURCE</b>	<b>TITLE AND DATE</b>
352.232-9	Withholding of Contract Payment (Apr 1984)
352.233-70	Litigation and Claims (Apr 1984)
352.242-71	Final Decisions on Audit Findings (Apr 1984)
352.270-7	Paperwork Reduction Act (Apr 1984)

## Section I-2 - Clauses Incorporated In Full Text

### I.2 FAR 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of contract expiration.

(End of Clause)

### I.3 FAR 52.229-8 Taxes -- Foreign Cost-Reimbursement Contracts (Mar 1990)

(a) Any tax or duty from which the United States Government is exempt by agreement with the Government of TBD, or from which the Contractor or any subcontractor under this contract is exempt under the laws of TBD, shall not constitute an allowable cost under this contract.

(b) If the Contractor or subcontractor under this contract obtains a foreign tax credit that reduces its Federal income tax liability under the United States Internal Revenue Code (Title 26, U.S. Code) because of the payment of any tax or duty that was reimbursed under this contract, the amount of the reduction shall be paid or credited at the time of such offset to the Government of the United States as the Contracting Officer directs.

(End of Clause)

### I.4 FAR 52.244-2 Subcontracts (Aug 1998)

(a) *Definitions.* As used in this clause—

“*Approved purchasing system*” means a Contractor’s purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR)

“*Consent to subcontract*” means the Contracting Officer’s written consent for the Contractor to enter into a particular subcontract.

“*Subcontract*” means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) This clause does not apply to subcontracts for special test equipment when the contract contains the clause at FAR 52.245-18, Special Test Equipment.

(c) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (d)( or (e) or this clause.

(d) If the contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that--

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the national Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For contracts awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(e) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts:

(f)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (c), (d), or (e) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting --

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's cost or pricing data in determining the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) or this clause.



(g) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination --

- (1) Of the acceptability of any subcontract terms or conditions;
- (2) Of the allowability of any cost under this contract; or
- (3) To relieve the Contractor of any responsibility for performing this contract.

(h) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(i) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(j) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(k) Paragraphs (d) and (f) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

(End of Clause)

## **I.5 FAR 52.244-6 Subcontracts for Commercial Items and Commercial Components (Oct 1998)**

(a) Definitions.

"Commercial item," as used in this clause, has the meaning contained in the clause at 52.202-1, Definitions.

"Subcontract," as used in this clause, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or non-developmental items as components of items to be supplied under this contract.

(c) Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:

- (1) 52.222-26, Equal Opportunity (E.O.11246);
- (2) 52.222-35, Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (38 U.S.C.4212(a));
- (3) 52.222-36, Affirmative Action for Workers with Disabilities (29 U.S.C.793); and
- (4) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C.1241) (flow down not required for subcontracts awarded beginning May 1, 1996).

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

(End of Clause)

## **I.6 HHSAR 352.202-1 Definitions (Apr 1984), Alternate I**

(a) The term “Secretary” or “Head of the Agency” (also called “Agency Head”) means the Secretary, Under Secretary, or any Assistant Secretary, Administrator or Commissioner, of the Department of Health and Human Services; and the term “his/her duly authorized representative” means any person, persons, or board authorized to act for the Secretary.

(b) The term “Contracting Officer” means a person with the authority to enter into, administer, and/or terminate contracts and make related determinations and findings. The term includes certain authorized representatives of the Contracting Officer acting within the limits of their authority as delegated by the Contracting Officer.

(c) The term “Project Officer” means the person representing the Government for the Purpose of technical monitoring of contract performance. The Project Officer is not authorized to issue any instructions or directions which effect any increases or decreases in the scope of work or which would result in the increase or decrease of the cost of this contract or a change in performance period of this contract. In addition, the Project Officer is not authorized to receive or act upon the Contractor's notification of a revised cost estimate pursuant to the Limitation of Cost or Limitation of Funds clause of this contract.

(d) The term “Department” means the Department of Health and Human Services.

(e) Except as otherwise provided in this contract, the term “subcontract” includes purchase order under this contract.

(End of Clause)

## **I.7 HHSAR 352.270-1 Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (Apr 1984)**

The Contractor agrees as follows:

(a) Planning. The Contractor will develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth below. This plan shall include a provision for ascertaining the number and types of disabled individuals planning to attend the meeting, conference, or seminar. The plan shall be submitted to the project officer for approval prior to initiating action. (A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars may be submitted in lieu of separate plans.)

(b) Facilities. Any facility to be utilized for meetings, conferences, or seminars in performance of this contract shall be accessible to persons with disabilities. The Contractor shall determine, by an on-site inspection if necessary, that the following minimum accessibility requirements are met, or suitable modifications are made to meet these requirements, before the meeting:

(1) Parking. (i) Where parking is available on or adjacent to the site, one 12' wide space must be set aside for the care of each mobility impaired attendee. The space need not be permanently striped but may be temporarily marked by signs, ropes, or other means satisfactory to carry out this provision.

(ii) Where parking is not available on or adjacent to the site, valet parking or other alternative means to assist a person who has a mobility impairment may be used. Alternate means must be satisfactory in the judgment of the Government project officer.

(2) Entrances. (i) "Entrances" shall include at least one accessible entrance from the street/sidewalk level, and at least one accessible entrance from any available parking facility.

(ii) The entrance shall be level or accessible by ramp with an incline that allows independent negotiation by a person in a wheelchair. In general, the slope of the incline shall be no more than 1" rise per foot of ramp length (1:12).

(iii) Entrance doorways shall be at least 30" in clear width and capable of operation by persons with disabilities. Revolving doors, regardless of fold-back capability, will not meet this requirement.

(3) Meeting Rooms. (i) Meeting room access from the main entrance area must be level or at an independently negotiable incline (approximately 1:12) and/or served by elevators from the main entrance level. All elevators shall be capable of accommodating a wheelchair 29" wide by 45" long.

(ii) Meeting rooms shall be on one level or, if on different levels, capable of being reached by elevators or by ramps that can be independently negotiated by a person in a wheelchair. Doorways to all meeting rooms shall be at least 30" in clear width.

(iii) The interior of the meeting room shall be on one level or ramped so as to be independently negotiable for a person in a wheelchair.

(iv) Stages, speaker platforms, etc. which are to be used by persons in wheelchairs must be accessible by ramps or lifts. When used, the ramps may not necessarily be independently negotiable if space does not permit. However, any slope over 1:12 must be approved by the project officer. Each case is to be judged on its own merits.

(v) If a meeting room with fixed seating is utilized, seating arrangements for persons in wheelchairs shall be made so that these persons are incorporated into the group rather than isolated on the perimeter of the group.

(4) Restrooms. (i) Restrooms shall have level access, signs indicating accessibility, and doorways at least 30" in clear width.

(ii) Sufficient turning space within restrooms shall be provided for independent use by a person in a wheelchair 29" wide by 45" long. A space 60" by 60" or 83" by 56" of unobstructed floor space as measured 12" above the floor is acceptable by standard; other layouts will be accepted if it can be demonstrated that they are usable as indicated.

(iii) There will be a restroom for each sex or a unisex restroom with at least one toilet stall capable of accommodating a wheelchair 29" wide by 45" long (by standard, the minimum is 3'-0" by 4'-8") with out-swinging doors or privacy curtains. Wall mounted grab bars are required.

(iv) When separate restrooms have been set up for mobility impaired persons, they shall be located adjacent to the regular restrooms and shall be fully accessible.

(5) Eating Facilities. (i) Eating facilities in the meeting facility must be accessible under the same general guidelines as are applied to meeting rooms.

(ii) If the eating facility is a cafeteria, the food service area (cafeteria line) must allow sufficient room for independent wheelchair movement and accessibility to food for persons in wheelchairs, and cafeteria staff shall be available to assist disabled persons.

(6) Overnight Facilities. If overnight accommodations are required:

(i) Sufficient accessible guest rooms to accommodate each attendee who is disabled shall be located in the facility where the meeting, conference, or seminar is held, or in a facility housing the attendees which is conveniently located nearby, whichever is satisfactory to the project officer.

(ii) Overnight facilities shall provide for the same minimum accessibility requirements as the facility utilized for the meeting, conference, or seminar. In addition, guest room access from the main entrance area shall be level, ramped at an independently negotiable incline (1:12), and/or served by elevators capable of accommodating a wheelchair 29" wide by 45" long.

(iii) Doorways to guest rooms, including the doorway to the bathroom, shall be at least 30" in clear width.

(iv) Bathrooms shall have wall mounted grab bars at the tub and water closet.

(v) Guest rooms for persons with a disability shall be provided at the same rate as a guest room for other attendees.

(7) Water Fountains. Water fountains shall be accessible to disabled persons, or have cup dispensers for use by persons in wheelchairs.

(c) Provisions of Services for Sensory Impaired Attendees. (1) The Contractor, in planning the meeting, conference, or seminar, shall include in all announcements and other materials pertaining to the meeting, conference, or seminar a notice indicating that services will be made available to sensory impaired persons attending the meeting, if requested within five (5) days of the date of the meeting, conference, or seminar. The announcement(s) and other material(s) shall indicate that sensory impaired persons may contact a specific person(s), at a specific address and phone number(s), to make their service requirements known. The phone number(s) shall include a teletype number for the hearing impaired.

(2) The Contractor shall provide, at no cost to the individual, those services required by persons with sensory impairments to insure their complete participation in the meeting, conference, or seminar.

(3) As a minimum, when requested in advance, the Contractor shall provide the following services:

(i) For hearing impaired persons, qualified interpreters. Provisions will also be made for volume controlled phone lines and, if necessary, transportation to local teletype equipment to enable hearing impaired individuals to receive and send meeting related calls. If local teletype equipment is not available, the Contractor shall provide on site teletype equipment. Also, the meeting rooms will be adequately illuminated so signing by interpreters can be easily seen.

(ii) For vision impaired persons, readers and/or cassette materials, as necessary, to enable full participation. Also, meeting rooms will be adequately illuminated.

(iii) Agenda and other conference material(s) shall be translated into a usable form for the visually and hearing impaired. Readers, Braille translations, and/or tape recordings are all acceptable. These materials shall be available to sensory impaired individuals upon their arrival.

(4) The Contractor is responsible for making every effort to ascertain the number of sensory impaired individuals who plan to attend the meeting, conference, or seminar. However, if it can be determined that there will be no sensory impaired person (deaf and/or blind) in attendance, the provision of those services under paragraph (c) for the non-represented group, or groups, is not required.

(End of Clause)

## Section J - List Of Attachments

<b><u>ITEM</u></b>	<b><u>NOMENCLATURE</u></b>	<b><u>NO. OF PAGES</u></b>
1	Billing Instructions for Negotiated Cost Type Contracts	3
2	Contractor Performance Report	4
3.	ACH Vendor/Miscellaneous Payment Enrollment Form	1
4	Privacy Act, Federal Register System Notification Number 09-200136/Vol. 57. No. 252/Thursday, December 31, 1992/Notices	5
5.	Standard Form 294 – Subcontracting Report for Individual Contracts (download form at: <a href="http://www.gsa.gov/forms/pdf_files/sf294.pdf">www.gsa.gov/forms/pdf_files/sf294.pdf</a> )	
6.	DHHS Small Business Subcontracting Plan Sample	7
7.	Standard Form 295 – Summary Subcontract Report (download form at: <a href="http://www.gsa.gov/forms/pdf_files/sf295.pdf">www.gsa.gov/forms/pdf_files/sf295.pdf</a> )	

## Section K - Representations, Certifications, And Other Statements Of Offerors

FAR SOURCE	TITLE AND DATE
52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (Apr 1991)
52.204-5	Women-Owned Business Other Than Small Business (May 1999)
52.222-21	Prohibition of Segregated Facilities (Feb 1999)

### K.1 FAR 52.204-3 Taxpayer Identification (Oct 1998)

(a) Definitions.

“Common parent,” as used in this solicitation provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

“Taxpayer Identification Number (TIN),” as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M and implementing regulations issued by the IRS. If the resulting contract is subject to the reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror’s relationship with the government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror’s TIN.

(d) Taxpayer Identification Number (TIN).

- ☐ TIN: \_\_\_\_\_.
- ☐ TIN has been applied for.
- ☐ TIN is not required because:
- ☐ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;
- ☐ Offeror is an agency or instrumentality of a foreign government;
- ☐ Offeror is an agency or instrumentality of a Federal Government;
- ☐ Other. State basis. \_\_\_\_\_

(e) Type of organization.

- ☐ Sole proprietorship;

- ☐ Partnership;
- ☐ Corporate entity (not tax-exempt):
- ☐ Corporate entity (tax-exempt):
- ☐ Government entity (Federal, State, or local);
- ☐ Foreign government;
- ☐ International organization per 26 CFR 1.6049-4;
- ☐ Other \_\_\_\_\_.

(f) Common Parent.

- ☐ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.
- ☐ Name and TIN of common parent:

Name \_\_\_\_\_

TIN \_\_\_\_\_

(End of Provision)

## **K.2 FAR 52.209-5 Certification Regarding Debarment, Suspension, Proposed Debarment, and Other Responsibility Matters (Mar 1996)**

(a)

(1) The Offeror certifies, to the best of its knowledge and belief, that --

(i) The Offeror and/or any of its Principals --

(A) Are ☐ are not ☐ presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have ☐ have not ☐, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are ☐ are not ☐ presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in subdivision (a)(1)(i)(B) of this provision.

(ii) The Offeror has ☐ has not ☐, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "*Principals*," for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment, and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror non-responsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of Provision)

### **K.3 FAR 52.215-6 Place of Performance (Oct 1997)**

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, ☐intends ☐ does not intend to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

<b>Place of Performance(Street Address, City, State, County, Zip Code)</b>	<b>Name and Address of Owner and Operator of the Plant or Facility if Other Than Offeror or Respondent</b>

(End of Provision)

### **K.4 FAR 52.219-1 Small Business Program Representations (May 1999)**

(a)

(1) The standard industrial classification (SIC) code for this acquisition is .

(2) The small business size standard is .



(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

*(b) Representations.*

(1) The offeror represents as part of its offer that it ☐ is, ☐ is not a small business concern.

(2) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it ☐ is, ☐ is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it ☐ is, ☐ is not a women-owned small business concern.

*(c) Definitions.*

*"Small business concern,"* as used in this provision, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

*"Women-owned small business concern,"* as used in this provision, means a small business concern --

(1) Which is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

*(d) Notice.*

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall --

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of Provision)

## **K.5 FAR 52.219-1 Alternate I (Nov 1999)**

(4) Complete only if offeror represented itself as small business concern in paragraph (b)(1) of this provision. The offeror represents, as part of its offer, that --

(i) It ☐ is, ☐ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no

material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR Part 126; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (b)(4)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture: . Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(End of Alternate)

## **K.6 FAR 52.219-22 Small Disadvantaged Business Status (Oct 1999)**

(a) General. This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit on this solicitation. Status as a small business and status as a small disadvantaged business for general statistical purposes is covered by the provision at FAR 52.219-1, Small Business Program Representation.

(b) Representations.

(1) General. The offeror represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either—

☐ (i) It has received certification by the Small Business Administration as a small disadvantaged business concern consistent with 13 CFR 124, Subpart B; and

(A) No material change in disadvantaged ownership and control has occurred since its certification;

(B) Where the concern is owned by one or more disadvantaged individuals, the net worth of each individual upon whom the certification is based does not exceed \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(C) It is identified, on the date of its representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration (PRO-Net); or

☐ (ii) It has submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(2) ☐ For Joint Ventures. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements at 13 CFR 124.1002(f) and that the representation in paragraph (b)(1) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture:

(c) Penalties and Remedies. Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or subcontract shall:

(1) Be punished by imposition of a fine, imprisonment, or both;

(2) Be subject to administrative remedies, including suspension and debarment; and

(3) Be ineligible for participation in programs conducted under the authority of the Small Business Act.

(End of provision)

## **K.7 FAR 52.222-22 Previous Contracts and Compliance Reports (Feb 1999)**

The offeror represents that --

(a) It ☐ has, ☐ has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;

(b) It ☐ has, ☐ has not filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

(End of Provision)

## **K.8 FAR 52.222-25 Affirmative Action Compliance (Apr 1984)**

The offeror represents that --

(a) It ☐ has developed and has on file, ☐ has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2); or

(b) It ☐ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of Provision)

## **K.9 FAR 52.225-8 Duty-Free Entry (Feb 2000)**

(a) *Definition.* "Customs territory of the United States" means the States, the District of Columbia, and Puerto Rico.

(b) Except as otherwise approved by the Contracting Officer, the Contractor shall not include in the contract price any amount for duties on supplies specifically identified in the Schedule to be accorded duty-free entry.

(c) Except as provided in paragraph (d) of this clause or elsewhere in this contract, the following procedures apply to supplies not identified in the Schedule to be accorded duty-free entry:

(1) The Contractor shall notify the Contracting Officer in writing of any purchase of foreign supplies (including, without limitation, raw materials, components, and intermediate assemblies) in excess of \$10,000 that are to be imported into the customs territory of the United States for delivery to the Government under this contract, either as end products or for incorporation into end products. The Contractor shall furnish the notice to the Contracting Officer at least 20 calendar days before the importation. The notice shall identify the—

(i) Foreign supplies;

(ii) Estimated amount of duty; and

(iii) Country of origin.

(2) The Contracting Officer will determine whether any of these supplies should be accorded duty-free entry and will notify the Contractor within 10 calendar days after receipt of the Contractor's notification.

(3) Except as otherwise approved by the Contracting Officer, the contract price shall be reduced by (or the allowable cost shall not include) the amount of duty that would be payable if the supplies were not entered duty-free.

(d) The Contractor is not required to provide the notification under paragraph (c) of this clause for purchases of foreign supplies if—

(1) The supplies are identical in nature to items purchased by the Contractor or any subcontractor in connection with its commercial business; and

(2) Segregation of these supplies to ensure use only on Government contracts containing duty-free entry provisions is not economical or feasible.

(e) The Contractor shall claim duty-free entry only for supplies to be delivered to the Government under this contract, either as end products or incorporated into end products, and shall pay duty on supplies, or any portion of them, other than scrap, salvage, or competitive sale authorized by the Contracting Officer, diverted to non-governmental use.

(f) The Government will execute any required duty-free entry certificates for supplies to be accorded duty-free entry and will assist the Contractor in obtaining duty-free entry for these supplies.

(g) Shipping documents for supplies to be accorded duty-free entry shall consign the shipments to the contracting agency in care of the Contractor and shall include the—

(1) Delivery address of the Contractor (or contracting agency, if appropriate);

(2) Government prime contract number;

(3) Identification of carrier;

(4) Notation "UNITED STATES GOVERNMENT, \_\_\_\_\_ [agency] \_\_\_\_\_, Duty-free entry to be claimed pursuant to Item No(s) \_\_\_\_\_ [from Tariff Schedules] \_\_\_\_\_, Harmonized Tariff Schedules of the United States. Upon arrival of shipment at port of entry, District Director of Customs, please release shipment under 19 CFR part 142 and notify [cognizant contract administration office] for execution of Customs Forms 7501 and 7501-A and any required duty-free entry certificates.";

(5) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight); and

(6) Estimated value in United States dollars.

(h) The Contractor shall instruct the foreign supplier to—

(1) Consign the shipment as specified in paragraph (g) of this clause;

(2) Mark all packages with the words "UNITED STATES GOVERNMENT" and the title of the contracting agency; and

(3) Include with the shipment at least two copies of the bill of lading (or other shipping document) for use by the District Director of Customs at the port of entry.

(i) The Contractor shall provide written notice to the cognizant contract administration office immediately after notification by the Contracting Officer that duty-free entry will be accorded foreign supplies or, for duty-free supplies identified in the Schedule, upon award by the Contractor to the overseas supplier. The notice shall identify the—

- (1) Foreign supplies;
- (2) Country of origin;
- (3) Contract number; and
- (4) Scheduled delivery date(s).

(j) The Contractor shall include the substance of this clause in any subcontract if—

(1) Supplies identified in the Schedule to be accorded duty-free entry will be imported into the customs territory of the United States; or

(2) Other foreign supplies in excess of \$10,000 may be imported into the customs territory of the United States.

(End of clause)

## **K.10 FAR 52.226-2 Historically Black College or University and Minority Institution Representation (May 1997)**

(a) *Definitions.* As used in this provision --

“*Historically Black College or University*” means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2. For the Department of Defense, the National Aeronautics and Space Administration, and the Coast Guard, the term also includes any nonprofit research institution that was an integral part of such a college or university before November 14, 1986.

“*Minority Institution*” means an institution of higher education meeting the requirements of Section 1046(3) of the Higher Education Act of 1965 (20 U.S.C.1135d-5(3)) which, for the purpose of this provision, includes a Hispanic-serving institution of higher education as defined in Section 316(b)(1) of the Act (20 U.S.C.1059c(b)(1)).

(b) *Representation.* The offeror represents that it --

☐ is ☐ is not a Historically Black College or University;

☐ is ☐ is not a Minority Institution.

(End of Provision)

## **K.11 FAR 52.227-7 Patents -- Notice of Government Licensee (Apr 1984)**

The Government is obligated to pay a royalty applicable to the proposed acquisition because of a license agreement between the Government and the patent owner. The patent number is \_\_\_\_\_, and the royalty rate is \_\_\_\_\_. If the offeror is the owner of, or a licensee under, the patent, indicate below:

☐ **Owner**

☐ **Licensee**

If an offeror does not indicate that it is the owner or a licensee of the patent, its offer will be evaluated by adding thereto an amount equal to the royalty.

(End of Provision)

## **K.12 FAR 52.227-15 Representation Limited Rights Data and Restricted Computer Software (May 1999)**

(a) This solicitation sets forth the work to be performed if a contract award results, and the Government's known delivery requirements for data (as defined in FAR 27.401). Any resulting contract may also provide the Government the option to order additional data under the Additional Data Requirements clause at 52.227-16 of the FAR, if included in the contract. Any data delivered under the resulting contract will be subject to the Rights in Data -- General clause at 52.227-14 that is to be included in this contract. Under the latter clause, a Contractor may withhold from delivery data that qualify as limited rights data or restricted computer software, and deliver form, fit, and function data in lieu thereof. The latter clause also may be used with its Alternates II and/or III to obtain delivery of limited rights data or restricted computer software, marked with limited rights or restricted rights notices, as appropriate. In addition, use of Alternate V with this latter clause provides the Government the right to inspect such data at the Contractor's facility.

(b) As an aid in determining the Government's need to include Alternate II or Alternate III in the clause at 52.227-14, Rights in Data -- General, the offer shall complete paragraph (c) of this provision to either state that none of the data qualify as limited rights data or restricted computer software, or identify, to the extent feasible, which of the data qualifies as limited rights data or restricted computer software. Any identification of limited rights data or restricted computer software in the offeror's response is not determinative of the status of such data should a contract be awarded to the offeror.

(c) The offeror has reviewed the requirements for the delivery of data or software and states (offeror check appropriate block) --

☐ *None of the data proposed for fulfilling such requirements qualifies as limited rights data or restricted computer software.*

☐ *Data proposed for fulfilling such requirements qualify as limited rights data or restricted computer software and are identified as follows:*

***Note: "Limited rights data" and "Restricted computer software" are defined in the contract clause entitled "Rights in Data -- General."***

(End of Provision)

## **K.13 FAR 52.230-1 Cost Accounting Standards Notices and Certification (Apr 1998)**

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS coverage pursuant to 48 CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

### **I. Disclosure Statement -- Cost Accounting Practices and Certification**

(a) Any contract in excess of \$500,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

☐ (1) Certificate of Concurrent Submission of Disclosure Statement. The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) Original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable; and

(ii) One copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the loose-leaf version of the Federal Acquisition Regulation.)

Date of Disclosure Statement: \_\_\_\_\_

Name and Address of Cognizant ACO or Federal Official Where Filed:

\_\_\_\_\_  
The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

☐ (2) Certificate of Previously Submitted Disclosure Statement. The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: \_\_\_\_\_

Name and Address of Cognizant ACO or Federal Official Where Filed:

\_\_\_\_\_  
The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

☐ (3) Certificate of Monetary Exemption. The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than \$25 million (of which at least one award exceeded \$1 million) in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

☐ (4) Certificate of Interim Exemption. The offeror hereby certifies that

(i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and

(ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of \$25 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

## II. Cost Accounting Standards -- Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

☐ The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than \$25 million in awards of CAS-covered prime contracts and subcontracts, or the offeror did not receive a single CAS-covered award exceeding \$1 million. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$25 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$25 million or more.

## III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

☐ yes    ☐ no

(End of Provision)



#### **K.14 Contact for Contract Negotiation/Administration (May 1998)**

Designate a person we may contact for contract administration in the event your firm receives a contract as a result of this solicitation:

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Address: \_\_\_\_\_  
(Street) (City) (State) (Zip Code)

Area Code: \_\_\_\_\_ Telephone: \_\_\_\_\_

Bidder/Offeror is located in \_\_\_\_\_ Congressional District.

Contract will be performed in \_\_\_\_\_  
(State) (City) (Congressional District)

#### **K.15 Certification (May 1998)**

TO BE COMPLETED BY THE OFFEROR: (The Offeror must check or complete all appropriate boxes or blanks in the Representations and Certifications contained herein). The Representations and Certifications must be executed below, by an individual authorized to bind the offeror.

The offeror makes the forgoing Representations and Certifications as a part of it's proposal.

\_\_\_\_\_  
(Name of offeror) (Solicitation Number)

\_\_\_\_\_  
(Signature of Authorized Individual) (Date)

\_\_\_\_\_  
(Typed Name of Authorized Individual)

Note: The penalty for making false statements in offerors is prescribed in 18 U.S.C. 1001.

## Section L - Instructions, Conditions, And Notices To Offerors

### L.1 FAR 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

<http://www.arnet.gov/far/>  
<http://farsite.hill.af.mil/vffar/htm>

(End of Provision)

<b>FAR SOURCE</b>	<b>TITLE AND DATE</b>
52.204-6	Data Universal Numbering System (DUNS) Number (Jun 1999)
52.214-34	Submission of Offers in the English Language (Apr 1991)
52.214-35	Submission of Offers in U.S. Currency (Apr 1991)
52.215-20	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data (Oct 1997)
52.215-20 Alternate I	(Oct 1997)
52.222-46	Evaluation of Compensation for Professional Employees (Feb 1993)

### L.2 FAR 52.215-1 Instructions to Offerors--Competitive Acquisition (Feb 2000)

(a) *Definitions.* As used in this provision—

“Discussions” are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer’s discretion, result in the offeror being allowed to revise its proposal.

“In writing” or “written” means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

“Proposal modification” is a change made to a proposal before the solicitation’s closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

“Proposal revision” is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

“Time,” if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted

in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show—

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii)(A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and —

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Proposals submitted in response to this solicitation shall be in English and in U.S. dollars, unless otherwise permitted by the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall —

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of—or in connection with—the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets *[insert numbers or other identification of sheets]*; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an

efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals .

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(e) The contract price shall not include any costs for insurance or contingency to cover losses, damage, injury, or death for which the Government is responsible under paragraph (a) of this clause.

(End of clause)

### **L.3 FAR 52.216-1 Type of Contract (Apr 1984)**

The Government contemplates award of a cost plus fix fee contract resulting from this solicitation.

(End of Provision)

### **L.4 FAR 52.233-2 Service of Protest (Aug 1996)**

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Centers for Disease Control and Prevention  
Procurement and Grants Office  
Contracts Management Branch  
2920 Brandywine Road, Suite 3000  
Attn: Susan Cleveland  
Atlanta, GA 30341

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

## **L.5 HHSAR 352.232-75 Incremental Funding (Apr 1984)**

(a) Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of Clause)

## **L.6 Inquiries (May 1998)**

Inquiries concerning the solicitation document should be submitted in writing to the issuing office. Any additions, deletions, or changes to the solicitation will be made by an amendment. OFFERORS ARE INSTRUCTED SPECIFICALLY TO CONTACT ONLY THE SOLICITATION CONTRACTING OFFICE IN CONNECTION WITH ANY ASPECT OF THIS REQUIREMENT PRIOR TO CONTRACT AWARD. PROPOSALS AND ALL CORRESPONDENCE RELATING TO THE SOLICITATION DOCUMENT SHALL BE SUBMITTED TO THE CONTRACTING OFFICE. Inquiries should be received at the Contracting Office no later than June 13, 2000, and maybe submitted via facsimile to (770) 488-2670/2671, via e-mail to knw9@cdc.gov or mailed hard copy to the address shown as the issuing office on the cover sheet of the solicitation.

(End of Provision)

## **L.7 Incurring Costs (May 1998)**

This solicitation does not commit the Government to pay any cost for the preparation and submission of a proposal. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

(End of Provision)

## **L.8 Alternate Proposals (May 1998)**

The offeror may, at its discretion, submit alternate proposals or proposals that deviate from this solicitation's requirements; provided that the offeror also submits a proposal for performance of the work as specified in the statement of work. Alternate proposals may be considered if performance would be improved or not compromised, and if they are in the best interest of the Government. Alternate proposals, or deviations from any requirements of this RFP, must be clearly identified.

(End of Provision)

## **L.9 General Instructions (Negotiated) (Jan 2000)**

(a) Offerors are invited to submit a proposal in response to this solicitation. All proposals received will become part of the official file.

(b) The following instructions establish the acceptable minimum requirements for the format and content of proposals.

(c) Your proposal must be prepared in separate parts as instructed herein. Each part shall be separate and complete in itself so that evaluation of one may be accomplished independently of evaluation of the other(s). The technical proposal (if required) must not contain reference to cost; however, resource information, such as data concerning labor hours and categories, material, subcontracts, etc., must be contained in the technical proposal so that your understanding of the Statement of Work can be evaluated. The technical proposal (if required) must disclose your technical approach in sufficient detail to provide a clear and concise presentation that addresses, but is not limited to, the requirements of the technical proposal instructions.

(d) The proposal must be signed by an official authorized to bind your organization. You must submit an original and 8 copies of your proposal to:

Centers for Disease Control and Prevention  
Procurement and Grants Office  
Contracts Management Branch  
2920 Brandywine Road, Suite 3000  
Atlanta, GA 30341  
Attn: Kem Williams  
Solicitation No. 2000-N-00073

(e) Offerors are requested to submit proposals, to the maximum extent possible, on high grade white paper which can be recycled.

(f) Facsimile proposals are not authorized unless this solicitation incorporates FAR 52.215-5, Facsimile Proposals, in Section L.

(g) The Government will evaluate proposals in accordance with the evaluation criteria set forth in Section M, Evaluation Factors for Award.

(End of Provision)

## **L.10 Technical Proposal Instructions (Feb 2000)**

(a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's statement of work will not be eligible for award. The technical proposal should be in as much detail as you consider necessary to reflect a clear understanding of the nature of the work being undertaken.

(b) The technical proposal must not contain reference to cost; however, resource information, such as data concerning labor hours and categories, material, subcontracts, etc., must be contained in the technical proposal so that your understanding of the statement of work can be evaluated.

(c) (1) The Technical Proposal shall not exceed 75 double-spaced, single-sided, standard 8-1/2 x 11 inch pages of 10 pitch type, excluding appendices and resumes of key people.

(2) The technical proposal should be prepared and submitted in a format to facilitate evaluation in accordance with the criteria specified in Section M of the RFP, i.e., the technical proposal should

contain: a) a separate section to address the offeror's understanding of the project; b) a separate section to address the offeror's proposed "methodology and approach"; c) a separate section to address the offeror's "management plan and personnel"; d) a separate section to address the offeror's "experience and capabilities"; and e) a separate section to address the offeror's "past performance".

- (3) The technical proposal shall be in the offeror's own words; and, shall include a clear and succinct statement of the scope, and objectives of this contract. The proposal shall demonstrate the offeror's complete understanding of the purpose, objectives, scope, and requirements of this contract, and address potential problems which may be encountered in performance of the contemplated work.
- (4) The Offeror shall provide a clear and succinct statement of the problem, purposes, and objectives of the project in the Offeror's own words as a demonstration of an adequate understanding of the intent and requirements of this contract.
- (5) The Offeror shall clearly describe proposed approaches to comply with the requirements of the Statement of Work. The proposal shall address proposed activities that must be carried out to effectively and efficiently achieve the stated purpose in Section C, Statement of Work. This will include phasing of tasks, methods to be used, scheduling of time and resources, and a milestone chart of the Offeror's proposed activities to achieve required deliverables and services within the contract period. The Offeror should fully describe potential problems that may be encountered in completing this contract, plans for handling contingencies that may arise, and factors that will influence the success of the project.
- (6) The Offeror shall describe their proposed plan for managing the resources necessary to comply with the requirements specified in the Statement of Work. This shall include a description of the project organization, including proposed person hours for each key individual.
- (7) The Offeror is requested to provide a curriculum vitae that details relevant training and experience for proposed professional personnel in such a way that it is clear that each individual has adequate qualifications to perform the work to be delivered. The Offeror shall indicate percentage of time that proposed key individuals are currently allocated to other projects and indicate the availability and commitment of these personnel at the effective date of the contract. In addition, the specific functions of each person and subcontractor assigned to various phases of the contract shall be described and related to their qualifications.
- (8) The Offeror is requested to provide audited financial statements and supporting documentation for the prior two calendar or fiscal years of operation on itself, or in the absence of such history, on any owners or entities which hold a majority of its stock, including information on revenues, losses, profitability, assets, and liquidity. Information should be included on pending or unsettled legal actions, including bankruptcy and civil or criminal litigation, and on any such actions resolved in the prior five years.
- (9) Evidence of prior collaboration with the Government and other organizations for similar research and development is very desirable and should be fully described. The Offeror shall list previous or ongoing Government or non-Government contracts, grants, or cooperative agreements related to medical device design and testing. This should include a brief description of the work, the performance period, the organization contracted or collaborated with, and the name and telephone number of an individual who may be contacted by the Government personnel to discuss the performance of the work. The Offeror also shall describe relevant current, pending, and planned research funding for principal personnel.
- (10) Past Performance Factor
  - a. Offerors shall submit the following information as part of their technical proposal for both the Offeror and proposed major subcontractors:



i. The Offeror shall provide a list of the last five (5) contracts completed during the past three years. And, the Offeror shall provide a list of all contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments, and commercial customers. Offerors that are newly formed entities without prior contracts should list and describe contracts and subcontracts performed by all key personnel while in the employ of other companies or organizations, as required above.

Provide the following information for each contract:

1. Name of Contracting Organization
2. Contract Number
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Completion date for past contracts
9. Proposed completion date for existing contracts

b. Each Offeror will be evaluated on their performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations and as an evaluation factor against which the Offeror's relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the contract under consideration. The Government is not required to contact all references provided by the Offeror, and references other than those identified by the Offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the Offeror's past performance.

(End of Provision)

## **L.11 BUSINESS PROPOSAL INSTRUCTIONS (APR 2000)**

The business proposal shall be comprised of the following elements:

### **(a) Contract Form and Representation and Certifications**

The contract form found in Part I, Section A, the completed Section B, and the Representations and Certifications contained in Part IV, Section K, of this Request for Proposals must be executed by an official authorized to bind the offeror.

### **(b) Contract Proposal Cover Sheet**

The cover sheet of your Business Proposal must comply with FAR Table 15-2, which requires the following information (as applicable):

- (1) Solicitation, contract, or modification number;
- (2) Name and address of offeror;
- (3) Name and telephone number of point of contact;
- (4) Name, address, and telephone number of Cognizant Contract Administration Office;
- (5) Name, address, and telephone number of Cognizant Audit Office;

- (6) Proposed cost, profit or fee (as applicable) per year and total for all years.
- (7) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31 , Cost Principles, and, if not, an explanation;
- (8) The following statement: “This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions set forth in FAR 15.403-5(b)(1) and FAR Table 15-2. By submitting this proposal, the offeror, if selected for discussions, grants to Contracting Officer or an authorized representative the right to examine, at any time prior to award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.”;
- (9) Date of submission;
- (10) Name, title, and signature of authorized representative.

(c) Cost Data Information

You must submit, as a minimum, a business proposal supported by detailed cost data. This cost data will be used to establish the reasonableness of the proposed amounts as well as to perform any required cost realism analysis. The business proposal shall itemize the individual costs, by phase (A through H) of the scope of work (Section C – Description/Specification/Work Statement, Subsection IV) that the offeror intends to perform. Inasmuch as it may be necessary to authorize performance of the project by phases or a group of phases, the extent that these are severable should be indicated, together with the effect, if any, of such severance upon the estimated cost (see paragraph L-11 below). **(Not all of the solicited eight phases A through H need be included in the proposal -- see paragraph L-13 below.)**

The itemized cost and the rationale for individual cost categories shall be furnished as follows:

(1) Direct Labor: Provide a time-phased (e.g., monthly, quarterly, annually, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish basis for labor hour and labor rate estimates (if direct labor rates are based on a current salary schedule, provide the salary schedule as an attachment. Otherwise, provide an excerpt of the current payroll register, tracing the individual or category to the rates being proposed);

(2) Fringe Benefits: Show fringe benefits as a separate cost category. Include the rate(s) and the method of calculating the fringe benefits. Provide a copy of the fringe benefit rate and institutional guidelines;

(3) Materials and Services: Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, price, and extent of competition;

(4) Subcontracted Items: Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all cost reimbursement type subcontracts. Include these analyses as part of your own cost submissions for subcontracts (see FAR Subpart 44.2 for information required to support a request for subcontract consent);

(5) Travel: Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for the proposed costs. A copy of your corporate travel policy shall be submitted with your proposal if travel costs have been proposed;

(6) Other Direct Costs: Provide a breakdown of all other costs not otherwise included in the categories listed above (e.g. computer services, consultant services, photocopying costs) and provide the basis for these proposed costs;

(7) Indirect Costs: Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Provide a copy of your current approved indirect cost rate agreement, including location and application of indirect cost rates to this proposal (including major subcontracts);

(8) Royalties: If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee: Name and address of licensor; Date of license agreement; Patent numbers; Patent application serial numbers; or other basis on which the royalty is payable; Brief description (including any part or model numbers of each contract item or component on which the royalty is payable); Percentage or dollar rate of royalty per unit; Unit price of contract item; Number of units; Total dollar amount of royalties; If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37);

(9) Facilities Capital Cost of Money: If you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

#### (d) Accounting System

In the event you do not have a Government approved accounting system and/or have never had a Government cost reimbursement contract, the following is required (include major subcontracts) to be submitted with your proposal:

(1) Description of your present accounting system and any changes contemplated as a result of your proposal;

(2) Make-up or basis for the indirect cost rate(s) you propose in response to this RFP;

(3) Current financial statement (balance sheet and/or profit and loss statement for the last two years).

#### (e) Other Administrative Data

(1) Your proposal must stipulate that it is predicated upon all the terms and conditions of this RFP. In addition, it must contain a statement to the effect that it is firm for a period of at least 60 days from the date of receipt by the Government;

(2) List name and telephone number of person to contact regarding your proposed accounting system;

(3) Your proposal must list any current commitments with the Government relating to the work or services and indicate whether these commitments will or will not interfere with the completion of work and services as contemplated under this proposal;

(4) Your proposal must identify any former HHS employee to be utilized on this project by providing the individual's name when employed by HHS, where employed, and the capacity in which employed;

(5) Your proposal must indicate whether you have the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. (If not, indicate the amount required and the anticipated source.);

(6) It is HHS policy that contractors provide all equipment and facilities necessary for performance of contracts; however, in some instances, an exception may be granted to furnish Government furnished property or to authorize purchase with contract funds. If additional equipment must be acquired, you must include in your proposal a description and the estimated cost of each item, and state whether you propose to furnish the item with your own funds. You must identify all Government-owned property in your possession that you propose to use in performing the prospective contract.

(7) The Optional Form 310, entitled, Protection of Human Subjects, Assurance Identification/ Certification/Declaration shall be completed, signed, and returned with your proposal if human subjects will be involved in any research activities;

(End of Provision)

## **L-10 52.215-20 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data. (OCT 1997), Alternate I (OCT 1997)**

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in

quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror may be required to submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2 .

(End of provision)

## **L.11 Severability of Phases and CDC Discretion**

CDC hereby notifies potential offerors that it reserves the right:

- 1) to negotiate with offerors to award contracts for fewer than all the solicited phases in proposals submitted;
- 2) to make multiple awards to different contract's for similar or different phases of work; or
- 3) to make no award at all in this or any subsequent fiscal year, according to its sole discretion, availability of funds, and its opinion as to the merit of proposals received.

(End of Provision)

## **L.12 HHSAR 352.270-8A Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (Jan 1999)**

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research contains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from

individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OPRR, (telephone: 301-496-7014), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

(f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

## **L.13 OPTIONAL SEVERABILITY OF CONTRACT PHASES**

**Not all of the solicited eight phases (Section C - Description/Specification/Work Statement, C-1., IV., phases A through H) need be included in the proposal. Companies or organizations that already have accomplished one or more of the phases contemplated in this solicitation may limit their submitted proposals to any or all of the subsequent phases in this solicitation. However, they must submit full documentation of the results and performance of any completed work (as well as prototype devices, which will be returned upon request) upon which they intend to base their proposed work.**

## Section M - Evaluation Factors For Award

### M.1 Technical Strength More Important than Cost/Price (Jan 2000)

(a) Offerors are advised that in proposal evaluation paramount consideration shall be given to technical proposals rather than cost or price unless, as a result of technical evaluations, proposals are judged to be essentially equal, in which case cost or price shall become the determining factor. Furthermore, cost/price will be evaluated on the basis of cost realism which is defined as the offeror's ability to project costs which are reasonable and indicate that the offeror understands the nature and extent of the work to be performed.

(b) Discussions, if held, will be conducted only with those offerors determined to be within the competitive range.

(c) Award shall be made to that responsible offeror submitting the proposal (Technical, Business and Past Performance) determined to be the most advantageous and the best value to the Government as evaluated under the criteria described in this Section.

(End of Provision)

### M.2 Evaluation of Proposals

This section is intended to explain the rationale and precise criteria by which proposals resulting from this solicitation will be evaluated. Offerors are advised that they are not restricted as to what is presented in their proposals, as long as sufficient materials is provided to allow evaluation of specific proposal elements defined below.

#### TECHNICAL EVALUATION CRITERIA

##### 1. UNDERSTANDING OF THE PROJECT (30 points)

The Government will evaluate the quality of the offerors demonstrated record of understanding in the design, research, development, and/or manufacturing of (1) needle-free injection devices or related technologies, (2) other devices in the biomedical engineering field which penetrate or deliver substances under the skin of humans or animals, or (3) other devices or instruments which involve the control and transfer of liquids through fine channels or orifices under high pressures.

Documentation demonstrating this record of experience and performance by the company or organization submitting the proposal (or its personnel to perform the contract ) must be included in the proposal.

The proposal shall demonstrate that the offerors plan to accomplish the effort is clear, feasible and practical, including recognition of potential difficulties in performance and appropriateness and soundness of proposed solutions.

##### 2. METHODOLOGY AND APPROACH (20 points)

The Government will evaluate the soundness, practicality and feasibility of the offeror's proposed methodology and approach to accomplishing the work expectations specified in the Statement of Work, including phasing of tasks, methods to be employed and methods for documentation, names and person hours for all personnel, and scheduling of time and resources.

A milestone chart should be included for the entire project. The offeror should clearly describe potential problems which may be encountered in completing each task and factors that will influence the success of the project. The proposal should demonstrate the availability of the resources needed to produce the required deliverables at the prescribed times.

##### 3. MANAGEMENT PLAN AND PERSONNEL (20 points)

The Government will evaluate the soundness, practicality and feasibility of the offeror's proposed management plan and personnel for accomplishing the work expectations of the Statement of Work. The offeror should describe the projects organization including (1) person hours and percentage of time for each key individual and (2) curriculum vitae detailing relevant training and experience for each key person in such a way that it is clear that each individual has adequate qualifications to perform the duties to be assumed. The functions of each key person, therefore, must be described and related to each individuals qualifications.

The offeror should indicate the percentage of time that proposed staff are currently allocating to other projects, the length of time these other projects will run, and the availability and commitment of these staff at the effective date of the contract and throughout the contract. An organization chart of the overall management schedule of critical events for the project also should be provided.

#### 4. EXPERIENCE AND CAPABILITIES (30 points)

The Government will evaluate the quality of the offeror=s (and proposed subcontractors) experience, qualifications, and technical ability relevant to (1) knowledge of existing vaccination device technology and immunization program requirements; 2) facilities and equipment; 3) the design and building of prototype vaccination devices; 4) testing and building of working vaccination devices for animal and human studies; 5) testing vaccination devices in animals, in human cadavers, and in human adults and children; 6) field testing of vaccination devices in measles endemic countries; 7) production of drawings and manufacturing specifications for mass production and commercial sale of vaccination devices, and submission of documentation to regulatory authorities for approval of marketing and sales, and 8) certification or not of the offerer's management practices and quality controls in conformance with ISO 9001 or equivalent standards.

The proposal must clearly demonstrate that the proposed Project Director is familiar with immunization programs, vaccine safety technology, and the methodology related to development and testing of vaccination devices in animal and human studies.

The proposal will demonstrate that project staff have experience in developing and testing vaccination devices and producing progress reports in a timely, efficient and accurate manner.

The proposal should clearly describe successful experience, if any, with previous or ongoing Government or non-Government contracts related to vaccination or related medical technologies. This should include a brief description of the work, the performance period, the organization contracted with, and the name and telephone number of an individual who may be contacted by the Government personnel to discuss the performance of the work.

The contractor shall be permitted to access special facilities or equipment in another organization in cases where the awardee enters into a subcontractual agreement with another institution for a portion of research and development work to be performed.

#### M.3 Past Performance Evaluation (Adjectival Rating System)(Nov 1999)

- (a) Past performance information will be evaluated in the following manner:
- (b) Each offeror shall be evaluated on its past performance under current and prior contracts. By past performance, the Government means the offeror's record of conforming to specifications and to standards of good workmanship; the contractor's record of forecasting and controlling costs; the offeror's adherence to contract schedules and terms, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer and degree of quality of deliverables and performance.



- (c) Past performance will not be scored, but the Government's conclusions about overall quality of the offeror's past performance will be highly influential in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered the most advantageous/best value to the Government.
- (d) The Government will focus on information that demonstrates quality of performance for similar services relative to the size and complexity of the procurement under consideration.
- (e) The Government will evaluate the quality of the offeror's past performance based on collaborated past performance evaluations included in the offerors proposal and/or other information obtained from references provided by the offeror, as well as other relevant past performance information obtained from other sources known to the Government. The Government may or may not survey all contracts listed by the offeror, and reserves the right to perform customer surveys only for those contracts which are deemed by the Government to be most relevant to this procurement. The Customer/Client Survey Letter and Past Performance Survey Document including as attachments under Section J will be used by the Government to gather any required past performance evaluations.
- (f) Evaluation of past performance will be a subjective assessment based on a consideration of all relevant facts and circumstances. It will not be based on absolute standards of acceptable performance.
- (g) The assessment of the offerors past performance will be used as a means of evaluating the relative capability of the offeror and the other competitors. Thus, an offeror with an exceptional record of relevant past performance may receive a more favorable evaluation than other whose records is acceptable and/or less relevant, even though both may have acceptable technical and business proposals.
- (h) An offeror without a record of past performance or for whom information on past performance is not available will not be evaluated favorably or unfavorably.
- (i) Information provided by Offerors, as requested under Section L herein, relating to problems encountered on the identified contracts and the Offeror's corrective actions will be considered when unfavorable reports of past performance are received. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of past performance information (e.g., relevance of an offeror's past performance information and adverse past performance which the offeror has not previously had an opportunity to respond). Communications may be held with Offerors to obtain additional information regarding adverse past performance when required for making a competitive range determination. If discussions are held, offerors will be given an opportunity to address unfavorable reports of past performance. Recent contracts will be examined to ensure that corrective measures have been implemented.
- (j) Past performance will be evaluated for only those offerors remaining in the competitive range after completion of the review of the business proposals and technical proposals.
- (k) Evaluation of past performance information will be reflected in terms of the following degrees of performance assessment:

Excellent: A significant majority of the sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again. Complaints are negligible or unfounded. Based on analyses of standard liquidity, activity, debt and profitability ratios, the offeror has been found to be in the best possible financial condition. No doubt exists that the offeror will successfully perform the Government's requirements as stated in the RFP.

Good: Most of the sources of information are consistently firm in stating that the offeror's performance was good, better than average, etc., and that they would willing do business with the offeror again. Complaints, though perhaps well-founded, are few and relatively minor. Based on analyses of standard liquidity, activity, debt and profitability ratios, the offeror has been found to be in a good financial condition. Little doubt exists that the offeror will successfully perform the Government's requirements as stated in the RFP.

Neutral: Either no past performance history exists for the corporation, predecessor companies, key personnel, or major/critical subcontractors, or the offeror's record of past performance was neither predominately favorable nor unfavorable. In the latter case, sources of information are roughly divided over the quality of the offeror's performance. While some state that they would do business with the offeror again, others are doubtful or would not. Complaints are balanced by reports of good work. Based on analyses of standard liquidity, activity, debt and profitability ratios, the offeror has been found to be in an adequate financial condition.

Marginal: Many sources of information made unfavorable reports about the offeror's performance and either express serious doubts about doing business with the offeror again or state that they would refuse to do so. However, there are some favorable reports, and some sources of information indicate that they would do business with the offeror again. There are many significant, serious, and well-founded complaints, but there are some reports of very good performance. Based on analyses of standard liquidity, activity, debt and profitability ratios, the offeror has been found to be on the brink of bankruptcy. Some doubt exists that the offeror will successfully perform the Government's requirements as stated in the RFP.

Poor: A significant majority of sources of information are consistently firm in stating that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again under any circumstance. Customer complaints are substantial or numerous and are well-founded. Based on analyses of standard liquidity, activity, debt and profitability ratios, the offeror has been found to be financially insolvent. Serious doubt exists that the offeror will successfully perform the Government's requirements as stated in the RFP.

(End of Provision)

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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## Billing Instructions for Negotiated Cost-Type Contracts Centers for Disease Control and Prevention

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**Introduction**

Reimbursement procedures related to negotiated cost-type contracts require that Contractors submit to the Government adequately prepared claims. The instructions that follow are provided for Contractors' use in the preparation and submission of invoices or vouchers requesting reimbursement for work performed. The preparation of invoices or vouchers as outlined below will aid in the review and approval of claims and enable prompt payment to the Contractor. All Task Orders issued under a contract must be broken down and identified on the invoice or voucher by Task Number.

**1. Forms to Be Used**

In requesting reimbursement, Contractors may use the regular Government voucher form, Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Continuation Sheet," or the Contractor's own invoice form. If the Contractor desires to use the Government's standard forms, a request for the forms should be submitted to the Contracting Officer. If the Contractor uses his own invoice, the billing must conform with the instructions set forth herein.

**2. Submission of Invoices or Vouchers**

Invoices or vouchers must be submitted *at least quarterly in an original and four (4) copies* to the following address:

Centers for Disease Control and Prevention  
Procurement and Grants Office, PGO  
Attention: Contracting Officer  
2920 Brandywine Road  
Room 3115, Mailstop K-18  
Atlanta, Georgia 30341

**REMINDER:** The original and each copy should be easily identifiable. Vouchers should be *collated*. Failure to submit vouchers in the proper format will delay your payment. Vouchers without proper number of copies will be returned.

### 3. Finance Office

The address of the paying office is as follows:

Financial Management Office  
Centers for Disease Control and Prevention  
1600 Clifton Road, Mailstop D-06  
Atlanta, Georgia 30333

*NOTE:* Do **not** send your invoices directly to the Financial Management Office. They must be processed through the Program Acquisition Branch.

### 4. Preparation of Invoices or Vouchers

#### a. *Summary of All Costs*

On the Standard Form 1034, a summary of all current costs **must** be shown. This summary consists of a list identifying the general categories and the amounts incurred during the period covered by the billing, together with the portion of fixed fee (if any) payable for that period. The reimbursable costs incurred and the dates of the period for which the charges are claimed must fall within the period specified in the contract.

#### b. *Details of Costs Claimed*

On the Standard Form 1035, a detailed breakdown **must** be provided to substantiate the categories shown on the summary of costs. The following describes some of the categories that might appear on your billings:

##### (1) **Direct Labor**

Direct Labor costs consist of salaries and wages paid for scientific, technical, and other work performed directly for the contract and pursuant to the contract terms. Labor costs, excluding fringe benefits and overtime premium pay, will be billed as follows:

*List the titles and amounts for employees whose salaries or wages, or portions thereof, were charged to the contract; show the rate (or hours) worked, and amount for each individual. The cost of direct labor which is charged directly to the contract must be supported by time records maintained in the contractor's office.*

##### (2) **Fringe Benefits**

If it is the Contractor's established practice to treat fringe benefits as a direct cost, such costs should be billed separately as a single item.

*NOTE:* Fringe benefits, bonuses, etc., are usually treated as indirect costs for inclusion in the overhead pool; however, they may be treated as direct labor costs or as an "Other Direct Charge" if such treatment is in accordance with the Contractor's established accounting procedures.

##### (3) **Materials and Supplies**

Only those items which the Contractor normally treats as "direct costs" should be claimed under this heading. Major classifications of material **only** should be billed separately under appropriate classification. Items costing less than \$25.00 may be listed by category of materials or supplies. Show the description and dollar amount of individual classifications. All such charges **must be supported** by the Contractor's office records.

##### (4) **Premium Pay**

Premium pay is the difference between the rates and amounts paid for overtime or shift work and amount normally paid on a straight time basis. Generally such pay is not included in the direct labor base and **should not be included** in the billing for "direct labor" unless the Contractor has consistently followed this practice in the past as a matter of policy. Premium pay of any kind unless provided for in the contract **must** be authorized by the Contracting Officer **in advance**. Billings for unauthorized premium pays have caused frequent delays in payment due to suspensions and exchange of correspondence. Citations of authorization for premium pay will avoid delays in payment. Authorized

premium pay may be shown as a single item on the summary of costs. However, it must be separately itemized for each position, or job category, showing the amount, and a citation of the Contracting Officer's letter of authorization on the continuation sheet of the invoice or voucher.

**(5) Travel**

When authorized in the contract as a direct cost, travel costs which are directly related to specific contract performance may be billed as a direct cost. Travel cost detail should show:

- (a) Name of traveller and official title,
- (b) Purpose of trip,
- (c) Dates of departure and return to starting point (station or airport),
- (d) Transportation costs, identified as to rail, air, private automobile (including mileage and rate) and taxi.
- (e) If claim for subsistence is on per diem basis, show number of days, rate and amount, as authorized in contract.<sup>1</sup> If claim is based on actual cost of subsistence, show, on a daily basis, the amounts claimed for lodging and meals separately.
- (f) Reference to Contracting Officer's letter of authorization if required by contract.

**(6) Consultant Fees**

Identify the consultant by name, number of days utilized, and amount of fee.

**(7) Equipment**

Nonexpendable personal property *must* be specifically approved in writing by the Contracting Officer or authorized by the terms of the contract. Billing data should include a description of item, make model, quantity, unit cost, total cost, and date approved by the Contracting Officer, if applicable. A copy of the vendor's bill may be submitted in lieu of the identifying information.

**(8) Burden**

Pending establishment of final contract indirect cost rates for each of the Contractor's fiscal years, the Contractor will be reimbursed based on his submittal of provisional rates as set forth in the contract. The contract may provide for more than one type indirect cost rate, such as overhead rate, and general and administrative expense rate, in which case the direct cost bases (e.g., direct labor, total direct cost, etc.)

**(9) Fixed Fee**

Ordinarily the fixed fee is stated in the contract as a lump sum and may be billed in the ratio of incurred costs to total estimated cost as set forth in the contract, with the final 15 percent to be billed on the final invoice or voucher. Contract terms govern the method of payments.

**c. Cumulative Amount Claimed**

On the attached Standard Form 1035, the Contractor must show the cumulative amounts claimed by categories from the contract award date through the date of the current invoice or voucher, as well as the estimated cost to complete per category.

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<sup>1</sup> For purposes of computing per diem charges in lieu of actual subsistence charges, unless otherwise provided in the contract, a day is divided into four quarters which begin at 12 midnight, 6:00 AM, 12 noon, and 6:00 PM. For example, at an authorized per diem rate of \$35.00 per day, a traveller who departed at 9:15 AM on July 15 and returned at 6:45 PM on July 18 would be entitled to \$131.25.

<b>PAST PERFORMANCE – CUSTOMER CLIENT SURVEY</b>	
<b>1. Contractor Name and Address:</b>	<b>2. Contract Number:</b>  <b>3. Contract Value (Base Plus Option):</b> <div style="border-bottom: 1px solid black; width: 100%;"></div> <b>4. Contract Award Date:</b> <div style="border-bottom: 1px solid black; width: 100%;"></div> <b>Contract Completion Date:</b> <div style="border-bottom: 1px solid black; width: 100%;"></div>
<b>5.</b> Type of Contract: (“X” all that apply) <input type="checkbox"/> FP <input type="checkbox"/> FP-EPA <input type="checkbox"/> CPFF - Completion <input type="checkbox"/> CPFF - Term <input type="checkbox"/> CPIF <input type="checkbox"/> CPAF <input type="checkbox"/> ID/IQ <input type="checkbox"/> BOA <input type="checkbox"/> Requirements <input type="checkbox"/> Labor Hour <input type="checkbox"/> T&M <input type="checkbox"/> SBSA 8(a) <input type="checkbox"/> SBIR <input type="checkbox"/> Sealed Bid <input type="checkbox"/> Negotiated <input type="checkbox"/> Competitive <input type="checkbox"/> Non-Competitive <input type="checkbox"/> Other (Specify)	
<b>6. Description of Requirement:</b>	
<b>7. Ratings.</b> Summarize contractor performance and place an “X” in the applicable bracket for the number which corresponds to the performance rating for each category. Please see page three for explanation of rating scale.	
<b>QUALITY OF PRODUCT OR SERVICE</b> Comments:	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5+ <input type="checkbox"/>
<b>VALUE and/or COST CONTROL</b> Comments:	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5+ <input type="checkbox"/>
<b>TIMELINESS OF PERFORMANCE</b> Comments:	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5+ <input type="checkbox"/>
<b>BUSINESS RELATIONS</b> Comments:	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/>

	3 <input type="checkbox"/> 4 <input type="checkbox"/> 5+ <input type="checkbox"/>
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<b>TOTAL</b>
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<b>8. EVALUATED BY</b>		
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A. NAME AND TITLE	B. SIGNATURE	C. DATE

D. ORGANIZATION NAME AND ADDRESS	TELEPHONE NO.:
	FAX NO.:
	INTERNET ADDRESS:

<b>9. CAPACITY IN WHICH THE CLIENT PERFORMED THIS CONTRACT:</b>	
_____ <b>Prime Contractor</b>	_____ <b>Subcontractor</b>

<b>10. WERE ABOVE PERFORMANCE RATINGS REVIEWED BY THE CONTRACTOR?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes	
Comments:	

## RATING GUIDELINES

Summarize contractor performance in each of the rating areas. Assign each area a rating of 0 (Unsatisfactory), 1 (Poor), 2 (Fair), 3 (Good), 4 (Excellent), or 5 (Plus). Use the following instructions as guidance in making these evaluations.

<u><b>Quality of Product/Service</b></u>	<u><b>Value/Cost Control</b></u>	<u><b>Timeliness</b></u>	<u><b>Business Relations</b></u>
<ul style="list-style-type: none"> <li>-Compliance with contract requirements</li> <li>-Accuracy of reports</li> <li>-Appropriateness of personnel</li> <li>-Technical excellence</li> </ul>	<ul style="list-style-type: none"> <li>-Current, accurate, and complete billings</li> <li>-Complaints concerning subcontractor and employee payments</li> <li>-Labor complaints</li> <li>-Price versus value (quality)</li> </ul>	<ul style="list-style-type: none"> <li>-Net interim milestones</li> <li>-Reliable</li> <li>-Responsive to technical direction</li> <li>-Completed on time, including wrap-up and contract administration</li> <li>-No liquidated damages assessed</li> </ul>	<ul style="list-style-type: none"> <li>-Effective Management</li> <li>-Businesslike correspondence</li> <li>-Responsive to contract requirements</li> <li>-Prompt notification of problems</li> <li>-Reasonable/cooperative</li> <li>-Flexible</li> <li>-Pro-active</li> <li>-Effective contractor recommended solutions</li> <li>-Effective small/small disadvantaged business subcontracting program</li> </ul>
<p><b>0. Unsatisfactory</b> Nonconformances are compromising achievement of contract requirements despite use of Agency resources</p>	Value issues are compromising performance of contract requirements	Delays are compromising the achievement of contract requirements, despite use of Agency resources.	Response to inquiries technical/service/admin issues are not effective and responsive
<p><b>1. Poor</b> Nonconformances require major Agency resources to ensure achievement of contract requirements</p>	Value issues require major Agency resources to ensure achievement of contract requirements	Delays require major Agency resources to ensure achievement of contract requirements	Response to inquiries technical/service/admin issues are marginally effective and responsive
<p><b>2. Fair</b> Nonconformances require minor Agency resources to ensure achievement of contract requirements</p>	Value issues require minor Agency resources to ensure achievement of contract requirements	Delays do not impact achievement of contract requirements	Response to inquiries technical/service/admin issues are usually effective and responsive
<p><b>3. Good</b> Nonconformances do not impact achievement of contract requirements</p>	Value issues do not impact achievement of contract requirements	Delays do not impact achievement of contract requirements	Response to inquiries technical/service/admin issues are usually effective and responsive
<p><b>4. Excellent</b> There are no quality problems</p>	There are no value issues	There are no delays	Response to inquiries technical/service/admin issues are effective and responsive



**5. PLUS** - The contractor has demonstrated an exceptional performance level in any of the above four categories that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as “Excellent”.

### **CONTRACTOR PERFORMANCE REPORT INSTRUCTIONS**

- Block 1: Contractor Name and Address. Identify the specific division being evaluated if there is more than one.
- Block 2: Contract number of contract being evaluated.
- Block 3: Contract value shall include base plus options. If funding was increased or decreased during the instant evaluation period, the value in this block should reflect the change.
- Block 4: Contract award date and anticipated or anticipated contract completion date.
- Block 5: Type of contract: Check all that apply.
- Block 6: Provide a brief description of the work and identify the key performance indicators. This description will allow agencies calling for reference checks to compare specifications.
- Block 7: Place an “X” in applicable bracket. Provide brief narrative for each category rated. Indicate contract requirements that exceeded minimum requirement, or those requirements that were not met and extent. Calculate the mean score rating.
- Block 8: Self Explanatory..
- Block 9: Self Explanatory.
- Block 10: Self Explanatory

**ACH VENDOR/MISCELLANEOUS PAYMENT ENROLLMENT FORM****Attachment J.3**

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program. Recipients of these payments should bring this information to the attention of their financial institution when presenting this form for completion.

**PRIVACY ACT STATEMENT**

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

**AGENCY INFORMATION**

FEDERAL PROGRAM AGENCY

**CENTERS FOR DISEASE CONTROL AND PREVENTION**AGENCY IDENTIFIER: **CDC**AGENCY LOCATION CODE (ALC): **7509-0421**ACH FORMAT: ☒ CCD+ ☐ CTX ☐ CTPADDRESS: **1600 CLIFTON ROAD NE M/S D16****ATLANTA, GA 30333**

CONTACT PERSON NAME:

**JENNIFER S. BRANNON**

PHONE:

**404/639-7441**

ADDITIONAL INFORMATION:

**PAYEE/COMPANY INFORMATION**

NAME

SSN OR TAXPAYER ID NO.

ADDRESS

CONTACT PERSON NAME:

PHONE:

**FINANCIAL INSTITUTION INFORMATION**

NAME:

ADDRESS:

ACH COORDINATOR NAME:

PHONE:

NINE-DIGIT ROUTING TRANSIT NUMBER:

DEPOSITOR ACCOUNT TITLE:

DEPOSITOR ACCOUNT NUMBER:

LOCKBOX NUMBER:

TYPE OF ACCOUNT:

☐ CHECKING☐ SAVINGSSIGNATURE AND TITLE OF AUTHORIZED OFFICIAL:  
(Could be same as ACH Coordinator)

PHONE:

## **PRIVACY ACT**

### **RECORD SYSTEM NUMBER: 09-20-0136**

System name: Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC/NCID.

Security classification: None.

System location: National Center for Infectious Diseases, Bldg. 1, Rm. 6013, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

San Juan Laboratories, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Calle Casa 2, San Juan, Puerto Rico 00921.

Arctic Investigations Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 4055 Tudor Center Drive, Anchorage, Alaska 99508.

Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Foot Hills Campus, Fort Collins, CO 80522.

National Center for HIV, STD and TB Prevention, Corporate Square, Bldg. 11, Rm. 2106, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

National Center for Environmental Health, Chamber Bldg. 101, Rm. 3116, Centers for Disease Control and Prevention, 4770 Burford Highway, NE, Atlanta, GA 30341-3724.

National Center for Injury Prevention and Control, Kroger/Vanderbilt Building, Rm. 1017B, Centers for Disease Control and Prevention, 4770 Burford Highway, NE, Atlanta, GA 30341-3724.

Epidemiology Program Office, Bldg. 1, Rm. 5046, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

Public Health Practice Program Office, Kroger/Williams Bldg., Rm. 3809, Centers for Disease Control and Prevention, 4770 Burford Highway, NE, Atlanta, GA 30341-3724.

National Center for Chronic Disease Prevention and Health Promotion, Kroger/Rhodes Bldg., Rm. 4000, Centers for Disease Control and Prevention, 4770 Burford Highway, NE, Atlanta, GA 30341-3724.

National Immunization Program, Corporate Square, Bldg. 12, Rm. 5113, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

and

Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

A list of contractor sites where individually identifiable data are currently located is available upon request to the appropriate system manager.

Categories of individuals covered by the system: Adults and children with diseases and other preventable conditions of public health significance; also included are control group participants. Workers employed by the Department of Energy and its predecessor agencies and their contractors are also included.

Categories of records in the system: Case reports, medical records, questionnaires, and related documents.

Authority for maintenance of the system: Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to grant assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)).

Purpose(s): This record system enables Centers for Disease Control and Prevention (CDC) officials to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: CDC is under contract with private firms for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records are maintained by such contractors. Contractors are required to maintain Privacy Act safeguards with respect to such records.

The following routine uses apply to all records in this system except those maintained under an assurance of confidentiality provided by Section 308(d) of the Public Health Service Act (unless expressly authorized in the consent form or stipulated in the Assurance Statement):

A record may be disclosed for a research purpose, when the Department:

(A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identified form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law;

(D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

Records may be disclosed to health departments and other public health or cooperating medical authorities in connection with program activities and related collaborative efforts to deal more effectively with diseases and conditions of public health significance.

Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

In the event of litigation where the defendant is: (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

Records may be disclosed by CDC in connection with public health activities to the Social Security Administration for sources of locating information to accomplish the research or program purposes for which the records were collected.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Computer tapes/disks and printouts and file folders.

Retrievability: By name of individual and by identification number.

Safeguards:

1. Authorized Users: A database security package is implemented on CDC's mainframe computer to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of the Centers for Disease Control and Prevention (CDC), or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.
  2. Physical Safeguards: Access to the CDC Clifton Road facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric keypad) system. Access to the data entry area is also controlled by a cardkey system. The hard copy records are kept in locked cabinets in locked rooms. The local fire department is located directly next door to the Clifton Road facility. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) are installed, and a proper mix of portable fire extinguishers are located throughout the computer room. The system is backed up on a nightly basis with copies of the files stored off site in a secure fireproof safe. Guard service in buildings provides personnel screening of visitors. Electronic anti-intrusion devices are in effect at the Federal Records Center.
  3. Procedural Safeguards: Protection for computerized records both on the mainframe and the CIO Local Area Network (LAN) includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and Vault Management System for secure off-site storage is available for backup tapes. To avoid inadvertent data disclosure, Adegaussing@ is performed to ensure that all data are removed from Privacy Act computer tapes and/or other magnetic media. Additional safeguards may be built into the program by the system analyst as warranted by the sensitivity of the data.
- CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts, and the CDC Project Director, contract officers and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.
4. Implementation Guidelines: The safeguards outlined above are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual; and Part 6, "Automated Information System Security," of the HHS Information Resources Management Manual. F.C. safeguards are in compliance with GSA Federal Property Management Regulations, Subchapter B--Archives and Records. Data maintained in CDC's Processing Center are in compliance with OMB Circular A-130, Appendix III. Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications. The CIO LANs currently operate under Novell v. 4.11 and are in compliance with ACDC & ATSDR Security Standards for Novell File Servers.@

Retention and disposal: Record copy of study reports are maintained in agency from two to three years in accordance with retention schedules. Source documents for computer are disposed of when no longer needed by program officials. Personal identifiers may be deleted from records when no longer needed in the study as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include erasing computer tapes, burning or shredding paper materials or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. Records are destroyed by paper recycling process when 20 years old, unless needed for further study.

System manager(s) and address: Director, National Center for Infectious Diseases, Bldg. 1, Rm. 6013, MS C12, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

Director, National Center for HIV, STD and TB Prevention, Corporate Square, Bldg. 11, Rm. 2106, MS E07, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

Director, National Center for Environmental Health, Chamber Bldg. 101, Rm. 3116, MS F29, Centers for Disease Control and Prevention, 4770 Burford Highway, NE, Atlanta, GA 30341-3724.

Director, National Center for Injury Prevention and Control, Kroger/Vanderbilt Building, Room 1017B, MS K02, Centers for Disease Control and Prevention, 4770 Burford Highway, NE, Atlanta, GA 30341-3724.

Director, Epidemiology Program Office, Bldg. 1, Rm. 5009, MS C08, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

Director, Public Health Practice Program Office, Kroger/Williams Building, Rm. 3809, MS K36, Centers for Disease Control and Prevention, 4700 Burford Highway, NE, Atlanta, GA 30341-3124.

Director, National Center for Chronic Disease Prevention and Health Promotion, Kroger/Rhodes Bldg., Rm. 4000, MS K40, Centers for Disease Control and Prevention, 4770 Burford Highway, NE, Atlanta, GA 30341-3724.

Director, National Immunization Program, Corporate Square, Bldg. 12, Rm. 5113, MS E05, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

Policy coordination is provided by: Associate Director for Management and Operations, Bldg. 16, Rm. 5117, MS D15, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.

Notification procedure: An individual may learn if a record exists about himself or herself or may obtain information concerning participation in epidemiological studies or surveillance activities by contacting the appropriate system manager at the address listed above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either: (1) submit a notarized request to verify their identity; or (2) certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a \$5,000 fine.

An individual who requests notification of or access to medical records shall, at the time the request is made, designate in writing a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of, or access to, a child's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child by means of a birth certificate or court order, as well as verify that he or she is who he or she claims to be.

The following information must be provided when requesting notification: (1) full name; (2) the approximate date and place of the study, if known; and (3) nature of the questionnaire or study in which the requester participated.

Record access procedures: Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An accounting of disclosures that have been made of the record, if any, may be requested.

Contesting record procedures: Contact the first official at the address specified under System Manager above, reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

Record source categories: Individuals, private physicians, State and local health departments, and other health care providers.

Systems exempted from certain provisions of the act: None.

- **DHHS SMALL, SMALL DISADVANTAGED, HUBZone AND WOMAN-OWNED SMALL BUSINESS SUBCONTRACTING PLAN**

**DATE OF PLAN:** \_\_\_\_\_

CONTRACTOR: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

DUNN & BRADSTREET NUMBER: \_\_\_\_\_

SOLICITATION OR CONTRACT NUMBER: \_\_\_\_\_

ITEM/SERVICE (Description): \_\_\_\_\_

\_\_\_\_\_

TOTAL CONTRACT AMOUNT:		\$ _____	\$ _____
		Total contract or	Option #1
		Base-Year, if options	(if applicable)
\$ _____	\$ _____	\$ _____	
Option #2	Option #3	Option #4	
(If applicable)	(if applicable)	(if applicable)	

TOTAL MODIFICATION AMOUNT, IF APPLICABLE \$ \_\_\_\_\_

TOTAL TASK ORDER AMOUNT, IF APPLICABLE \$ \_\_\_\_\_

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): \_\_\_\_\_

The following is a suggested model for use when developing subcontracting plans as required by P.L. 95-507 and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this model plan has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable; however, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. Further, the use of this model is not intended to waive other requirements that may be applicable under statute or regulation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.



**1. Type of Plan** (check one)

\_\_\_\_\_ Individual plan (all elements developed specifically for this contract and applicable for the full term of this contract.)

\_\_\_\_\_ Master plan (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

\_\_\_\_\_ Commercial products/service plan, including goals, covers the offerer's fiscal year and applies to the entire production of commercial items or delivery of services sold by either the entire company or a portion thereof (e.g. division, plant, or product line); this includes planned subcontracting for both commercial and government business.

**2. Goals**

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) and "Other" than small business (OTHER) as subcontractors, for the base year and each option year, as specified in FAR 19.704 (break out and append option year goals, if applicable) or project annual subcontracting base and goals under commercial plans.

a. Total estimated dollar value of ALL planned subcontracting i.e., with ALL types of concerns under this contract is \$ \_\_\_\_\_

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB and HUBZone): (% of "a")  
\$ \_\_\_\_\_ and \_\_\_\_\_%

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") \$ \_\_\_\_\_ and \_\_\_\_\_%

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") \$ \_\_\_\_\_ and \_\_\_\_\_%

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") \$ \_\_\_\_\_ and \_\_\_\_\_%

f. Total estimated dollar and percent of planned subcontracting with "OTHER" THAN SMALL BUSINESSES: (% of "a") \$ \_\_\_\_\_ and \_\_\_\_\_%

g. Provide a description of the method used to develop the subcontracting goals for small, small disadvantaged, woman-owned and HUBZone small businesses concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to small, small disadvantaged, woman-owned and HUBZone small business concerns were determined and how the capabilities of these concerns were considered for subcontract opportunities. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

h. Indirect costs have \_\_\_\_ have not \_\_\_\_ been included in the dollar and percentage subcontracting goals above. (check one)

i. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to small, small disadvantaged, woman-owned, and HUBZone small business concerns.

Provide a description of ALL the products and/or services, to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply.)

Product/Service	Other	SB	SDB	WOSB	HUBZone

### 3. Program Administrator :

NAME/TITLE:

ADDRESS:

TELEPHONE/E-MAIL:

**Duties:** Has general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans. Other duties include, but are not limited to, the following activities:

- a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to small, small disadvantaged, woman-owned and HUBZone small business concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing.

- b. Developing and maintaining bidder source lists of small, small disadvantaged, woman-owned and HUBZone small business concerns from all possible sources;
- c. Ensuring periodic rotation of potential subcontractors on bidder's lists;
- d. Ensuring that requests for contracts (RFC) are designed to permit the maximum practicable participation of small, small disadvantaged, woman-owned and HUBZone small businesses;
- e. Accessing various sources for the identification of small, small disadvantaged, woman-owned and HUBZone small businesses concerns to include the SBA's PRO-"Net" System, the Federal Acquisition Computer Network (FACNET) Contractor Registration Data Base, the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices;
- f. Establishing and maintaining contract and subcontract award records;
- g. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc;
- h. Ensuring that small, small disadvantaged, woman-owned and HUBZone small business concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;
- i. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Public Law 95-507 on purchasing;
- j. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;
- k. Preparing, and submitting timely, required subcontract reports;
- l. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies, and;
- m. Other duties: \_\_\_\_\_

#### 4. Equitable Opportunity

Describe efforts the offeror will make to ensure that small, small disadvantaged, woman-owned and HUBZone small business concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

- a. Outreach efforts to obtain sources:
  - 1) Contacting minority and small business trade associations;
  - 2) Contacting business development organizations and local chambers of commerce;
  - 3) Attending small, small disadvantaged, woman-owned and HUBZone small business procurement conferences and trade fairs;

- 4) Requesting sources from the Small Business Administrations (SBA) PRO-“Net”, and other SBA resources, and;
  - 5) Conducting market surveys to identify new sources.
- b. Internal efforts to guide and encourage purchasing personnel:
- 1) Conducting workshops, seminars, and training programs;
  - 2) Establishing, maintaining, and utilizing small, small disadvantaged, and woman-owned and HUBZone small business source lists, guides, and other data for soliciting subcontractors, and;
  - 3) Monitoring activities to evaluate compliance with the subcontracting plan.
- c. Additional efforts:

## 5. Flow Down Clause

- The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns", in all acquisitions exceeding the simplified acquisition threshold that offer further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of \$500,000 (\$1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c).)

## 6. Reporting and Cooperation

- The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) Submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and attendant Optional Form 312, SDB Participation Report and SF-295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 95.
- 

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	SF-294/of 312	4/30
Apr 1 - Sept 30	SF-294/of 312	10/30
Oct 1 - Sept 30	SF-295	10/30

Special instructions for commercial products plan: SF295 Report is due on 10/30 each year for the previous fiscal year ended 9/30.

- (a) Submit SF-294 and attendant optional Form 312 to: cognizant Contracting Officer
- (b) Submit SF-295 to cognizant contracting officer and to the:  
 Office of Small and Disadvantaged Business Utilization  
 Department of Health and Human Services  
 200 Independence Avenue, SW

Subcontracting Plan (Rev. October 1999)

Humphrey H. Building, Room 517-D  
Washington, D.C. 20201

(c) Submit "info" copy to SBA Commercial Market Representative (CMR); visit the SBA at <http://www.sba.gov/gc> and click on assistance directory to locate your nearest CMR.

## **7. Record keeping**

The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

- a. Small, small disadvantaged, woman-owned and HUBZone small businesses source lists, guides and other data identifying such vendors;
- b. Organizations contacted in an attempt to locate small, small disadvantaged, and woman-owned and HUBZone small business sources;
- c. On a contract-by-contract basis, records on all subcontract solicitations over \$100,000, which indicate for each solicitation (1) whether small business concerns were solicited, and, if not; (2) whether HUBZone small business concerns were solicited, if not, why not and (3) whether small disadvantage business concerns were solicited, if not, why not; (4) whether woman-owned small business concerns were solicited, and if not, why not; and (5) the reason for the failure of solicited small, small disadvantaged, and woman-owned and HUBZone small business concerns to receive the subcontract award;
- d. Records to support other outreach efforts, e.g., contracts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;
- e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program & requirements, and;
- f. On a contract-by-contract basis, records to support subcontract award data including the name address, and business type and size of each subcontractor. (This item is not required for company or division-wide commercial products plans.)
- g. Additional records:

## **SIGNATURE PAGE**

(applies to Master or Commercial type plans)

**This master or commercial type subcontracting plan is submitted by:**

**Contractor:**

**Contractor Signature:**

**Typed Signature:**

**Title:**

**Date Prepared:**

**And Is Accepted By:**

**Agency:**

**Contracting Officer Signature:**

**Typed Name:**

**Date:**